Reuss, Vicki A. (CDC/NIOSH/EID)

From: Lentz, Thomas J. (CDC/NIOSH/EID)
Sent: Friday, August 29, 2008 8:57 AM
To: Miller, Diane M. (CDC/NIOSH/EID)
Cc: Reuss, Vicki A. (CDC/NIOSH/EID)
Subject: FW: NIOSH Draft Control Banding Document Posted
Attachments: Stoffenmanager validatie _artikel AOH__2.pdf; Stoffenmanager manuscript main revised.pdf; Tables_rev.pdf; Figure2_rev.gif; Figure1_rev.gif

Diane and Vicki,

Here is one of the submissions I mentioned which should be added to Docket 138. Thanks and my apologies for the delay in forwarding.

T.J.

From:
Sent: Thursday, May 22, 2008 7:52 AM
To: Lentz, Thomas J. (CDC/NIOSH/EID)
Subject: RE: NIOSH Draft Control Banding Document Posted

Dear Thomas,

Thxs for the info. There is lot going one in the US about reviewing CB. I have been frequently in contact with David Zalk regarding his work. Both important work in the discussion/acceptance/evaluation of CB tools!

Please find enclosed some comments with emphasis on providing you with the latest updates and references on the Stoffenmanager tool:
- enclosed are two papers: a) Stofenmanager manuscript main, explaining the basis model; paper has been revised and submitted again to the Annals; we expect that it will be accepted soon (I will keep you informed)
b) Stoffenmanager validation study; paper has very recently been accepted by the Annals.
- would it be possible to incorporate these recent published results in the review? The references and some content now mentioned are not quite up to date (no surprise, because of recent developments)
- page 55. Arbo Unie (a Dutch Occupational Health Service), Expert Centre for Chemical Risk Management.
This whole paragraph could be updated;
* see the enclosed papers: Stoffenmanager now also performs a validated quantitative exposure assessment, thus not only being a qualitative prioritisation/control banding tool. In the next version 3.5 (july 2008) this will be possible for both dusts and liquids. For the present version 3.0 this is possible for dusts (see www.stoffenmanager.nl; english version). Please note also that Stoffenmanager has been accepted under the REACH regulation for quantitative exposure asessment.
* the Dutch have plans ..industry version". These plans have been completed and some 8 branchespecific versions have been developed and are online (in Dutch only, however the Stoffenmanager Construction is on request in English too). See for further explanation the "main article, Further developments of Stoffenmanager.

- section 2.1.9.1 is in my opinion for Stoffenmanager not correct. "Stoffenmanager predicts exposures …in the absence of any control". This is not the case. The user can choose in the exposure model from a picklist containing control measures either in the near or far field. Indeed, he also has the opportunity to choose no control measures at all. And also in the Netherlands it is rare to find workplaces without any control.

- at the moment we have some 8000 users of the generic Stoffenmanager. The branchespecific versions will be used by tenthousands of users.

- we now see that we have 2 types of users: a) SME's who are more interested in the control banding/prioritisation part; b) experts, who in addition are also interested in quantitative exposure assessment. We are planning for the next version 4.0 (end of this year, however funding not yet 100% guaranteed) that the Stoffenmanager will be "split" for both users (and perhaps a shortcut for quantitative estimations). How this will look like and what this means for the user interface is part of the project.

Well, a lot of info. I hope that this can be of help in your excellent review work.

Best regards,

Van: Lentz, Thomas J. (CDC/NIOSH/EID) [mailto:tbl7@cdc.gov]
Verzonden: woensdag 14 mei 2008 14:49

Dear Control Banding ITG members,

I want to inform you that the NIOSH draft Control Banding Document (***Qualitative Risk Characterization and Management of Occupational Hazards (Control Banding [CB]): A Literature Review and Critical Analysis***) has been posted to the NIOSH Web site. The document may be accessed at http://www.cdc.gov/niosh/review/public/138/ during a public review and comment period of approximately 90 days.

Best regards,

T.J. Lentz
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"Stoffenmanager", a web-based control banding tool using an exposure process model.

Background and introduction

The rules for assessing and managing risks of dangerous substances in the workplace have been laid down in several European Directives, such as the Framework Directive (Council Directive 89/391), the Carcinogens Directive (Council Directive 90/394/EEC) and the Chemical Agents Directive (Council Directive 98/24/EC). However, keeping these rules is not easy, as several authors from different EU member states have stressed (Maidment, 1998, Nieminen, 1998, Tijssen and Links, 2002, Balsat *et al.*, 2003). Further research on chemical risk factors and risk management in small and medium sized enterprises (SMEs) are among the top priorities in Europe in relation to occupational safety and health (European Agency for Safety and Health at Work, 2000). The Dutch Ministry of Social Affairs and Employment has established a four year programme to assist SMEs in reinforcing the working conditions policy on hazardous substances, the so-called "VASt-programme" (http://vast.szw.nl, Hollander, 2003). Industry sectors, product chains and companies could obtain financial support for action plans aimed at implementation of improvements through this programme. Furthermore, a set of projects has been carried out to provide the industry with effective tools to assess and control exposure to dangerous substances.

The control banding tool for inhalation exposure was developed to help companies without specific expertise in chemical risk assessment to prioritize their potential risks of chemicals and to indicate the types of exposure controls that could lower these risks. Such a tool classifies exposure situations into risk, control or priority bands, based on classification systems for the hazards of the substances and the exposure and controls in the situations. The development of the tool started with an inventory of available approaches in Europe. A number of approaches were studied, including COSHH Essentials (Russel *et al.*, 1998), a "safety check" developed by the German BIA (Kittel *et al.*, 1996), a "support making decision tool" in development in France (Vincent and Bonthoux, 2000) and a method for "Chemische Arbeitsstoffe" by the Austrian AUVA (AUVA, date unknown).
The instruments were all evaluated against the following criteria:

- directed at hazardous substances;
- directed at the SME employer;
- part of a larger improvement process;
- relevant for risk assessment and control.

All instruments appeared to offer useful elements. However, it was decided that a new instrument would best fit the needs of SMEs in The Netherlands. Therefore, instead of "simply" translating one of the foreign instruments, a new instrument was built, based on previous work published by other groups. In this way, it represents a combination of useful elements from different sources.
Briefly, the "hazard banding" part of the tool is based on COSHH Essentials (Brooke, 1998), the exposure model on an approach published by Cherrie *et al.* (1996) and Cherrie and Schneider (1999) and the "risk banding" part is made by combining hazard bands with exposure bands resulting from the exposure model. The structure of the

Stoffenmanager was derived from a software tool (ChemAudit) which assists SMEs in controlling risks due to exposure to hazardous substances (Heussen *et al.*, 2002).

In this publication the priority ranking of the Stoffenmanager version 3.5 will be briefly described. The focus of the publication is on the part qualitative scoring part of the inhalation exposure model, because this is the most innovative part of the tool. This version of the Stoffenmanager has been evaluated using a large scale validation study (Tielemans *et al.* 2008). It also includes a quantification of exposure that is also described in Tielemans *et al.* (2008). Some (future) developments of Stoffenmanager will be briefly indicated in this publication.

The Stoffenmanager also contains a risk banding module for dermal exposure. The core of this module is the RISKOFDERM Toolkit (Goede *et al.*, 2003, Oppl *et al.*, 2003, Schumacher-Wolz *et al.*, 2003, Warren *et al.*, 2003), which is incorporated in the Stoffenmanager. Because of the integration in the total tool some questions that are in the RISKOFDERM Toolkit do not appear in the dermal part of Stoffenmanager, because they are already covered in the general hazards part or the inhalation exposure part. This does not influence the actual risk assessment for dermal exposure. The dermal feature will not be discussed further in this paper.

General framework of the Stoffenmanager

The basic element of the Stoffenmanager is risk banding. However, some other useful elements are included as well. The Stoffenmanager is a web-based tool and is currently available in English and Dutch (www.stoffenmanager.nl). The user enters data in web-based forms. Data are kept confidential and can only be accessed and used by the user by logging in with his user name and password. Use of the Stoffenmanager is free of charge. The general structure of the tool is presented in figure 1.

Input of basic data

The Stoffenmanager prioritizes exposure to products. These may be preparations (e.g. a paint), but can also be pure substances. Basic data on the products can be entered manually or (largely) from a database with product information, using a standard exchange format. Part of the information, such as the Risk and Safety phrases according to the Safety Data Sheet (SDS), is not directly used in the risk banding model, but is used for other features, e.g. for the derivation of more user friendly workplace instruction cards based on the information in the SDS. The following information has to be entered:

- Name of the product
- Publication date of the SDS
- Whether the substance is a solid or a liquid
    - For a solid: the dustiness
    - For a liquid, the vapour pressure
- Supplier of the product
- Departments in which the product is used
- Composition of the product, according to the SDS
- Hazard categories (*i.e.* symbols according to the SDS)
- Personal protective equipment and ventilation needed (according to the SDS)

- Risk and Safety phrases (R/S phrases for the product [*i.e.* not for the individual components], according to the SDS)

The vapour pressure for products (i.e. not pure substances) as mentioned on the SDS is used, when available. When no vapour pressure is mentioned for the product as a whole, but a vapour pressure for a main ingredient is given, that value can be entered. If no vapour pressure is available at all, the option "unknown" has to be chosen. In that case the vapour pressure of water at 20 °C is chosen as default value.

A choice of "dustiness" of the product has to be made by the user of the Stoffenmanager to allow the exposure model to take account of this parameter in establishing the exposure band (see later).

The input of the departments where the substance is used is needed to prepare the output of specific registration information for carcinogens, mutagens and reprotoxic agents.

Hazard banding

The hazard band of each substance is based on the R-phrases entered. For this purpose, the division of R-phrases in hazard bands of COSHH Essentials is used. The original hazard bands are described by Brooke (1998). A few modifications have been made since that publication to accommodate changes in the European Directives. An overview of the hazard bands can be found in the documentation on COSHH Essentials at http://www.coshh-essentials.org.uk.

Exposure banding

The exposure model used for exposure banding in the Stoffenmanager is based on the ideas published by Cherrie *et al.* (1996) and further developed by Cherrie and Schneider (1999). These ideas are used and adapted in several ways. The resulting model used in the Stoffenmanager is discussed in the next part of this publication. The exposure model leads to a classification in one of four exposure bands.

Risk banding

The results from the hazard and exposure banding steps are combined in the Stoffenmanager to produce risk bands. The Stoffenmanager only provides a relative ranking of risks. No quantitative comparison between exposure levels and hazard levels is made, because in the present version both exposure and hazards are only classified in relative bands. The result of the risk banding is therefore a "priority band". It was decided to make three priority bands, because less bands would lead to too limited discrimination, while more bands would suggest more precision than warranted. he combination of hazard and exposure into priority or risk bands in the Stoffenmanager is presented in figure 2. The classification of situations into priority or risk bands is based on the bands of hazard and exposure. Allocation into risk bands was done in such a way that exposure to very high hazard substances, such as carcinogenic substances or substances that lead to respiratory sensitization, would lead to a high priority, unless the exposure was very limited (leading to medium priority). The intention is to ensure that these substances and their use and control are considered specifically and in more detail by the user and to encourage the substitution by less dangerous substances. Also, very high exposures should generally lead to high priority, unless the hazard of the substances is very low.

The further allocation was done to ensure a generally increasing risk band with increasing combination of exposure and hazard. Final allocations were, of course, partly arbitrarily. When all situations within a company with exposure to substances have been assessed, the total overview of the risk banding for all these substances and situations provides a semi-quantitative risk assessment for the whole company.

Control scenario

When a situation is evaluated and a priority band is assigned, Stoffenmanager enables the user to design a risk reduction scenario or control scenario. This option leads to a list of possible control measures that can be taken. To guide the user towards control measures that are expected to ensure the best reduction, the control measures are presented in the order of the so-called "STOP-principle" (Substitution, Technical measures, Operational measures, Personal protection). The user first has to consider the possible control measures of the first group, before he can go on to the control measures of the second group, etcetera. The following (generic) control measures can be chosen in the system in the order as indicated:

- control measures at the source
    - removal of the hazardous product from the task
    - removal of the task from the process
    - modification of the product form
    - modification of the task, e.g. instead of "frequent handling" the task can be modified to "handling in closed systems"
    - replacement of the product by another product with a different composition, changing the hazard and possibly also the exposure
    - automation of the process, leading to a whole new exposure assessment
    - changing the order of tasks, e.g. adding powder to liquid instead of the other way around
- control measures in an area directly around the source
    - placing the source in a containment in the room (full enclosure)
    - adding local exhaust ventilation to emission sources
    - combination of local exhaust ventilation and full enclosure
    - limiting the emission of a product (e.g. wetting powder)
- modifying controls in the wider work area of the worker
    - creating and ensuring natural ventilation
    - installing a (mechanical) area ventilation system
    - use of a spray cabin
- control of the situation of the worker
    - use of work cabins (with or without ventilation with clean air supply)
    - use of personal protective equipment

Depending on the choice of control measure, some of the inputs need to be re-evaluated to adopt the hazard or exposure bands for the chosen control measures. The new priority band is then calculated based on the modified inputs.

Because the exposure model leads to a classification into exposure bands, it is possible that a control measure that will lead to a reduction in exposure will not lead to a lower exposure band (and related priority band). In such cases this is reported in the results of the control scenario and the user is recommended to consider implementing the control measure, even if it may not lead to a lower priority band.

Action plan

The modified inputs of a control scenario can be saved in an action plan. The tool itself does not choose the control measures. The choice of the control measures that a user wants to put in the action plan is up to the user. The tool will indicate whether these control measures have an effect on the priority band of the situations. There is an option to download the information into a document including elements to be filled in locally, e.g. who is responsible for the action, the estimated costs and the deadline for finalizing the action.

Workplace instruction cards

For all products Stoffenmanager can generate so-called workplace instruction cards. This is a more readable and more user friendly version of the information taken over from the Safety Data Sheet. In addition the user has to specify the personal protective equipment, storage instructions and control measures in the case of accidental spillage.

Registration of carcinogenic, mutagenic and reprotoxic substances

There are specific legal requirements in The Netherlands for registering the carcinogenic, mutagenic and reprotoxic substances used in the workplace. This includes: the number of workers exposed, the amount of the substance available in the workplace and the type of activities done with the substance. When a carcinogenic, mutagenic or reprotoxic substance is entered into the Stoffenmanager, the user can add this information in his data set to build up a registry of such substances. The user is also asked to indicate the control measures used to control exposure and the reasons why this substance cannot be substituted or removed from the process. This registry can be used to have a quick overview of the situation regarding these substances and to show to the authorities when required.

Information for the storage of dangerous substances

Information and guidance regarding the storage of dangerous substances in accordance to the guidelines in The Netherlands can also be entered and evaluated through the Stoffenmanager. This will not be discussed further in the present publication.

Explosion safety

Stoffenmanager also enables the user to assess explosion risks in the workplace (according to the European ATEX guidelines) and to choose control measures which can be transferred to an action plan. This module will not be discussed further in the present publication either.

Exposure model in the Stoffenmanager

The exposure model used for the classification into exposure bands is based on a model presented by Cherrie and Schneider (1999), which was based on earlier work by Cherrie *et al.* (1996). The exposure algorithm follows a source-receptor approach and incorporates modifying factors related to source emission and dispersion of contaminants.

Exposure is represented as a multiplicative function of type of handling, intrinsic properties of the product, local controls and general ventilation.
Cherrie *et al.* (1996) have made categories, running from 'none' to 'very high' for each parameter and given these categories a score on a logarithmic scale, running from 0 through 0.03, 0.1, 0.3, 1 and 3 to 10. A score of 1 is considered to be the default value that leads to a certain concentration. Values above 1 indicate situations with increased exposure and values below 1 situations with reduced exposure. A logarithmic scale for categories leads to a reasonable dispersion of resulting exposure levels or scores over the categories, in accordance with the logarithmic distribution that exposure levels often are found to have.

The model presented by Cherrie and Schneider (1999) has been modified on a few points to build a model that is suitable for use by SME employers, who are non-experts in occupational hygiene. Modifications have been made regarding the emission scores. New descriptions have been made for types of handling to make the descriptions more easily understandable and assignable to non-experts. The intrinsic emission scores have also been modified to enable a more user-friendly relation between type of product and intrinsic emission. Also, the emission of near-field and far-field sources was made the same to simplify the algorithms. Finally, a fixed background factor was added. Details of the final model are presented below.
A source of emission that is relatively far from a worker has a lower influence on the exposure of the worker than a source very close to the worker. Cherrie and Schneider (1999) have therefore distinguished the 'near-field' emissions, which take place very close to the worker, from the 'far-field' emissions that occur further away from the worker. They also present a separate equation for the 'far-field' sources. They define the 'near-field' as a cube around the head of the worker with dimensions of 2 by 2 by 2 meter. A source is inside the 'near-field' according to the Stoffenmanager if it is within a distance of 1 meter from the head of the worker. This defines the 'near-field' as a sphere instead of a cube. Because the main purpose of the Stoffenmanager is to rank situations relative to their risk, an additional factor was added for frequency and duration of the task. The categorisation of parameters and the allocation of scores for categories in the Stoffenmanager is partly taken from the work by Cherrie *et al.* (1996). Where categories or definitions have been changed from the published versions, the final allocations were largely made by expert judgement.

The modified model as used in the new version of the Stoffenmanager is represented by the following equations.

$$B = C_t \cdot t_h \cdot f_h \qquad (1)$$

$$C_t = (C_{ds} + C_{nf} + C_{ff}) \cdot \eta_{imm} \qquad (2)$$

$$C_{ds} = E \cdot a \qquad (3)$$

$$C_{nf} = E \cdot H \cdot \eta_{lc} \cdot \eta_{gv\_nf} \qquad (4)$$

$$C_{ff} = E \cdot H \cdot \eta_{lc} \cdot \eta_{gv\_ff} \qquad (5)$$

The final equation of the exposure model of Stoffenmanager is:

$$B = \{[E \cdot H \cdot \eta_{lc\_nf} \cdot \eta_{gv\_nf}] + [E \cdot H \cdot \eta_{lc\_ff} \cdot \eta_{gv\_ff}] + [E \cdot a]\} \cdot \eta_{imm} \cdot t_h \cdot f_h \qquad (6)$$

where: B = exposure score
C_t = total concentration (score)
t_h = duration of the handling
f_h = frequency of the handling
C_{ds} = background concentration (score) due to diffusive sources
C_{nf} = concentration (score) due to near field sources
C_{ff} = concentration (score) due to far field sources
η_{imm} = multiplier for the reduction of exposure due to control measures at the worker
E = intrinsic emission score
a = multiplier for the relative influence of background sources
H = handling (or task) score
η_{lc} = multiplier for the effect of local control measures
η_{gv_nf} = multiplier for the effect of general ventilation in relation to the room size on the exposure due to near field sources
η_{gv_ff} = multiplier for the effect of general ventilation in relation to the room size on the exposure due to far field sources

Of course, SME employers are not able to use the equations presented above. Therefore, each of the parameters was specified in relatively simple parameters to create a useful model.

Intrinsic emission

Intrinsic emission ('E' in equations (3) to (6)) is a substance related parameter in the exposure model of the Stoffenmanager. It relates to the vapour pressure of liquids and the dustiness of powders.

For liquids E is directly related to the vapour pressure. This continuous factor is chosen to be the same as the evaporation factor used in the "AWARE" code (Krop and van Broekhuizen, 2006). This code has been developed in The Netherlands in the scope of the so-called "VASt-programme" to assist companies in choosing products with lower risks. The intrinsic emission is calculated as:

$$E = P_{product} / 30{,}000 \qquad (7)$$

where: E = the intrinsic emission for a product;
$P_{product}$ = the vapour pressure of the product (Pa).

The idea behind this calculation is that E represents a relative evaporation factor. Substances with a vapour pressure of 30,000 Pa or more are fully evaporated in a very short time and will practically only be available as vapour. Substances with lower vapour pressures evaporate relatively slower and more of these substances may be present in the form of liquid product, therefore not being available for inhalation. The vapour pressure of a product can be derived in different ways. If available, e.g. on the Safety Data Sheet, the vapour pressure of the product itself can be used. If the liquid part of a product largely consists of one substance, the vapour pressure of that substance can be used. This could e.g. be done for a paint product where the only hazardous substance mentioned on the Safety Data Sheet is a mineral spirit with a weight percentage of 20-50% in the paint. The vapour pressure of this substance can be used as such (approximately 350 Pa) to calculate the relevant emission factor weighted by the percentage of that substance in the product. If a product contains two or three volatiles that make up large parts of the product, one could derive a "percentage weighted" intrinsic emission of the product according to equation (8).

$$E = (P_1/30{,}000)\cdot f_1 + (P_2/30{,}000)\cdot f_2 + (P_3/30{,}000)\cdot f_3 \quad (8)$$

Where: P_i = the vapour pressure of substance i
f_i = the fraction of substance i in the product

For a product with mineral spirits with a vapour pressure of 350 Pa in a concentration of 15% and naphtha with a vapour pressure of 690 Pa in a concentration of 30% and no other volatile substances, the calculated intrinsic emission to enter into Stoffenmanager would be $(350/30{,}000)\cdot 0.15 + (690/30{,}000)\cdot 0.30 = 0{,}00865$. It is recognized that, ideally, the mole fraction of a substance in a mixture should be used instead of a mass fraction. In general, however, there is only limited information on characteristics of the mixture available. For pragmatic reasons we therefore rely on less precise but more accessible information.

Finally, if the above presented methods are not possible or not practicable, the vapour pressure can be presented as "unknown" in which case the value for water at 20 °C (2300 Pa) will be used. This default is chosen from a conservative point of view, since it is unlikely that the vapour pressure of the critical compound in the mixture will be higher than the vapour pressure of water.

When the Stoffenmanager is used to prioritise exposures for single components from products, the intrinsic emission for the single substance can be calculated as:

$$E_i = (P_i / 30{,}000)^* f_i \quad (9)$$

where: E_i = the intrinsic emission for a specific component in the product;
f_i = the fraction of the specific component in the product;
P_i = the vapour pressure of the pure substance (Pa).

For dustiness of solids (powders) no direct relation with physical parameters is at hand. In analogy to the Cherrie model a table with weighing factors for different descriptions of dusts was developed. The user will have to determine this parameter himself by comparing the observed dustiness with the descriptions of the categories of dusts in the

Stoffenmanager. The scores for intrinsic emission of solid substances are presented in Table 1.

Handling

The scores for handling ('H' in equations (4) to (6)) are related to a number of processes that may influence emission. These processes can be described in physico-chemical terms, such as evaporation, frictional forces, etc. In a specific model for a specific set of tasks, e.g. in a branch-specific Stoffenmanager, the handling can be described in detail in a language understandable to SME employers. This is much more difficult in a generic model. Descriptions and discriminating categories, that are expected to be understandable to the user of the model, were made to capture these exposure processes. The scores for handling are described in Table 2a for liquids and in Table 2b for solids.

Near-field and far-field sources

A source is considered to be in the near-field ('nf' in equations (2), (4) and (6)) if it is within 1 meter of the head of the worker. A far-field source ('ff' in equations (2), (5) and (6)) is made recognizable to users by asking whether other workers in the room are doing the same task or whether there is a period of evaporation, hardening or drying of products on a surface (after application) that is left in the work area of the worker. To simplify the model, it is assumed that the same handling is conducted in the far field as in the near field. In addition, no distinction is made between one or multiple co-workers in the far field or continuous presence of co-workers versus presence during only part of the time. The emission of a far-field source due to a period of evaporation, hardening or drying will be restricted to products with a vapour pressure above 10 Pa.

Reduction of transmission

Reduction of transmission from the source towards the worker is possible in several ways. In the Stoffenmanager this is split into two factors: local control measures (n_{lc} in equations (4) to (6)) and general ventilation (η_{gv} in equations (4) to (6)). Both can have different options for near-field and far-field sources, as indicated by $\eta_{lc.nf}$ versus $\eta_{lc.ff}$ in equations (4) to (6). However, to simplify the model, it is assumed that the same local controls are used for near-field and for far-field sources. The scores for local controls used for near-field and far-field sources are presented in Table 3. The scores for general ventilation are different for near-field and far-field sources. These scores are related to the room volume and are taken from Cherrie (1999), who based the values on simulations. They are presented in Tables 4a and 4b.

Background emissions

The far-field sources can be distinguished by the answers to the questions in the Stoffenmanager on co-workers doing activities with the same substance or product and on emission due to evaporation, hardening or drying of a substance or product after application. However, there can also be sources dispersed through the work area that are not covered by these questions. Such sources can be leaking machinery, contaminated rags lying around the room, spills that have not been cleaned up, etc. Therefore, an additional factor was added for background emissions in the model (C_{ds} in equations (2) and (3)). In the model it is a basic assumption that the exposure (and the background sources) has to be related to the intrinsic emission of the product. Therefore, it was decided to use a factor directly related to the intrinsic emission factor (a in equation (3)). In this way, the background emission of high volatile substances would be higher than that of low volatile substances. A (small) factor is defined, dependent on the regularity of inspection of machines and on the cleaning procedures in the work area. The scores are presented in Table 5. By using the background emissions through a small additional emission factor, its influence is insignificant for activities with high direct emissions, but becomes more apparent when there are hardly any direct emissions as seen from the handling scores. As the impact of diffusive sources on exposure level is extremely difficult to predict we decided to keep this part of the equation as simple as possible. Therefore a general ventilation parameter was not incorporated in the diffusive source component.

Modification for reduction of immission and duration and frequency of the task

The score that is obtained by summing up the three elements of emission (near-field, far-field and background) is corrected for the reduction of immission ('η_{imm}' in equations (2) and (6)). The reduction of immission in this model can be accomplished by means of separating the worker from the source or by using personal protective equipment (PPE). The first measure is slightly different from segregating the source from the worker. Instead of putting a source in a specific room, the workers are put in a specific room (e.g. a control room) for most of their working day. They only enter the area where the real production takes place for specific activities. The worker can also be placed in a closed cabin (e.g. in a tractor cabin while spraying pesticides). The scores for reduction of immission are presented in Table 6.

Another option to limit immission is the use of personal protective equipment (PPE). For this purpose the assigned protection factors as presented in a document of the Dutch Occupational Hygiene Society on selection and use of respiratory protection were used as a basis (NVvA, 2001). These scores are presented in Table 7.

The Stoffenmanager prioritizes separate tasks with products, based on the exposure related to the product and the task and the hazards related to the products. Some tasks may occur only a part of the work shift. This is accounted for by modification of the exposure score based on duration of the task during a working day and frequency of the task (year-based). The calculated exposure score is based on the assumption that a task is being performed during 8 hours a day with a frequency of 5 days per week (totally 40 hours per week). In this situation the factor "duration times frequency of task" is 1. If a task is being performed during fewer hours per day and/or in a lower frequency than 5 days per week, a linearly proportional reduction of the factor "duration times frequency of task" is used. In practice, task duration and exposure duration may not be the same. A concentration of a contaminant in work room air may be reduced slowly due to limited ventilation. However, it was decided that it would make the model too complicated if this kind of effect was to be taken into account specifically. Again, we have decided for user-friendliness at the loss of some precision.

The scores for duration and frequency of exposure are presented in Tables 8 and 9.

The modification of the scores obtained from the three emission sources by taking into account the reduction of immission, the duration and the frequency of exposure leads to a final exposure score. This exposure score is not used directly, because the score itself is not an exposure level and because using the scores directly for ranking situations would suggest more precision than is warranted with a tool like this. Therefore, the final exposure scores have been assigned to exposure bands according to Table 10.

Further developments of the Stoffenmanager

A number of future developments of the Stoffenmanager is presented below to indicate what increase in usefulness of the tool is expected soon.

Branch-specific versions

The present Stoffenmanager is a generic tool for use in all kinds of companies. It is therefore not tailored to specific needs of specific branches. Stimulated by the VASt programme, several branches, including artists, surface treatment (metal), cleaning, metal fabrication and engineering industry, construction industry (sub-sectors plastering and tiling), dentistry, textile and carpet manufacture, flooring and carpet laying industry have started to develop their own version of the Stoffenmanager, usually based on the previous version of the Stoffenmanager. These branch-specific tools will be made available only to companies in the branch. The branch-specific tools can have specific modifications that may include:

- using default tasks for the parameter ‘handling’;
- a list of default control measures for specific tasks;
- using known reduction factors to evaluate the effectiveness of control measures;
- quantification of exposure levels for certain tasks based on measured values;
- an integrated product-database to allow easy input of basic product data;
- branch specific hazard bands for toxic substances released during a process;
- a branch specific risk banding system for skin exposure.

A general feature of the branch-specific versions is that the language of the tool is tailored to the terminology of the branch.

Other developments

A number of other developments of the tool are already incorporated or planned for the (near) future:

- Inclusion of fact sheets and PIMEX (Picture Mix Exposure) videos on exposure control measures (generic or branch-specific).
- Extraction of data from Stoffenmanager about products, their use and the control measures as (part of) exposure scenarios under REACH (http://ecb.jrc.it/).
- Quantification of the exposure model of the Stoffenmanager using an extensive set of dedicated measurements together with existing exposure data gathered from several sources (Tielemans, *et al.*, 2008). The quantified version can e.g. be used in exposure assessments for REACH.
- Validation of the quantified model with independent, newly gathered exposure data (Schinkel *et al.*, 2008).

- Development of a web-based exposure database to collate exposure data for calibration and improvement of the Stoffenmanager exposure model in the future (STEAMbase: STOffenmanager Exposure And Modelling database).

Discussion and conclusions

The Stoffenmanager is an easy to use tool that plays an important role in the Dutch 'VASt'-programme. There are now more than 6600 registered users of the Stoffenmanager. After implementation of the branches-pecific Stoffenmanagers this number is expected to increase rapidly. This tool apparently fills a need in The Netherlands as is also shown by the development of several specific Stoffenmanagers for industry branches.

The Stoffenmanager is not the answer to all questions regarding risks of dangerous substances in SMEs. Presently, it is limited to prioritizing risks in a rather generic way, coupled with advice on general risk management measures and some other useful elements. It cannot fully fill all the needs of the rules for risk assessment at the workplace (e.g. the so-called "Chemical Agents Directive 98/24/EC).

The usefulness of the tool depends on its validity, its outputs, as well as on its user-friendliness. The hazard banding part of the Stoffenmanager is largely the same as that of the widely accepted COSHH Essentials tool. The exposure model is different. It is based on published approaches (Cherrie and Schneider, 1999), including an evaluation of the processes from source emissions to exposures.

Some modifications to the approaches of Cherrie and Schneider (1999) were made. The handling scores are derived from more user-friendly questions. Substantial expert judgement was used to cluster and describe tasks in understandable groups and to allocate scores to the handling. Using more (examples) of handling descriptions increases the user friendliness. A consistent allocation of intrinsic emission scores is probably facilitated by the use of our more understandable classes. We consider the changes in definition of 'near field' of relatively limited influence. However, the fact that we give the same emission score and local control score to 'far field' sources as to the 'near field' source is a simplification that can have substantial implications. It is not always logical that work done by others in the same area is similar to the work done by the assessed worker. This may lead to both over- and underestimation of exposure band. Finally, the addition of a background factor is probably an improvement. It caters for situations where diffusive sources are very important and only influences situations with very limited handling related emissions.

Several of the boundaries between categories had to be chosen in a rather arbitrary manner, because of a lack of information on the relation between the parameters and exposure levels. While some boundaries are clear-cut (e.g. room volumes), others are described only qualitatively (dustiness index) to allow non-expert users to use the tool with information that they have available. It is not possible to evaluate every boundary and every choice within such a tool in-depth based on real exposure data.

The model has been evaluated with a rather large set of measured data and was shown to perform quite well. The evaluation showed Spearman correlation coefficients between Stoffenmanager scores and exposure measurements that appear to be good for handling solids ($r_s = 0.80$; $N = 378$; $P < 0.0001$) and liquid scenarios ($r_s = 0.83$; $N = 320$; $P <$

0.0001). Mixed effect regression models with natural log-transformed Stoffenmanager scores as independent parameter explained a substantial part of the total exposure variability (52% for solid scenarios and 76% for liquid scenarios) (Tielemans *et al.*, 2008). These results provide reassurance that the model overall performs quite well. The results cannot be used to evaluate the influence of single parameters or choices in scores. The adequacy of the final priority bands for discriminating between situations with true risks and situations with adequate control is difficult to evaluate. A good relation between exposure scores and exposure levels is a positive starting point. However, the final adequacy also depends on the hazard bands and there is very limited information to indicate how well the categorisation of R-phrases in hazard bands works. A future evaluation of the total adequacy of the Stoffenmanager could study what the relation is between the assigned priority band and the exceedance of occupational exposure limits.

An important wish of users of the Stoffenmanager is to enable its use for comparison of (quantitative) exposure levels with occupational exposure limits. The quantification described by Tielemans *et al.* (2008) enables such a comparison, although it is not yet integrated directly into the software of the tool. A further extension may be to directly improve the model estimates with measured exposure levels for the situation under study through a Bayesian method. Such a new modelling approach has been proposed by Creely *et al.* (2005). We are currently investigating the possibilities of this approach, both for a large scale "advanced exposure model" (Tielemans *et al.*, 2007) with a built-in exposure database as well as for a small scale option for users to fill in a few own measurement results to improve on their own assessment.

Both the Ministry of Social Affairs and Employment and the industry invested a substantial amount of money and/or time in the development of the 'VASt'-programme and the development of the Stoffenmanager. The industry in The Netherlands is willing to improve the working conditions on dangerous substances, especially when this can be done in a pragmatic manner with useful tools. Due to its central position within the 'VASt'-programme, Stoffenmanager functions as a crystallization point for several other developments. In the future, other tools can be integrated in, or linked to the Stoffenmanager (or its specific versions).
The development of several specific variants of the Stoffenmanager raises the question whether in the future all these variants can still be called "Stoffenmanager". Their internal engine may still be largely similar, but their outside skin and several specific elements may lead to very different tools. This is not a real problem, as long as the quality of the tools is ensured. Whether or not a tool is still a version of the Stoffenmanager is not a real issue; much more important is the fact that the development of the Stoffenmanager has facilitated a whole range of further developments of useful tools for SMEs.

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Stoffenmanager exposure model:

development of a quantitative algorithm

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Abstract

In the Netherlands, the web-based tool called "Stoffenmanager" was initially developed to assist small and medium-sized enterprises (SMEs) to prioritize and control risks of handling chemical products in their workplaces. The aim of the present study was to explore the accuracy of the Stoffenmanager exposure algorithm. This was done by comparing its semi quantitative exposure rankings for specific substances with exposure measurements collected from several occupational settings to derive a quantitative exposure algorithm. Exposure data were collected using two strategies. First, we conducted 7 surveys specifically for validation of the Stoffenmanager. Second, existing occupational exposure data sets were collected from various sources. This resulted in 378 and 320 measurements for solid and liquid scenario's, respectively. The Spearman correlation coefficients between Stoffenmanager scores and exposure measurements appeared to be good for handling solids ($r_s = 0.80$; $N = 378$; $P < 0.0001$) and liquid scenarios ($r_s = 0.83$; $N = 320$; $P < 0.0001$). However, the correlation for liquid scenarios appeared to be lower when calculated separately for sets of volatile substances with a vapour pressure > 10 Pa ($r_s = 0.56$; $N = 104$; $P < 0.0001$) and non-volatile substances with a vapour pressure ≤ 10 Pa ($r_s = 0.53$; $N = 216$; $P < 0.0001$). The mixed effect regression models with natural log-transformed Stoffenmanager scores as independent parameter explained a substantial part of the total exposure variability (52% for solid scenarios and 76% for liquid scenarios). Notwithstanding the good correlation the data show substantial variability in exposure measurements given a certain Stoffenmanager score. The overall performance increases our confidence in the use of the Stoffenmanager as a generic tool for risk assessment. The mixed effect regression models presented in

this paper may be used for assessment of so called reasonable worst case (RWC) exposures. This evaluation is considered as an ongoing process and when more good quality data become available the analyses described in this paper will be expanded. Based on these analyses the algorithm will be refined in the near future.

Introduction

Important drivers of the development of generic and user friendly approaches for assessment of workplace health risks are the introduction of the Chemical Agents Directive (European Commission, 1998) and, more recently, the REACH legislation in Europe (European Commission, 2006). As exposure is a complex process and varies enormously between workers and over time (Kromhout *et al.*, 1993), the assessment of chemical risks requires a logical strategy or tool to focus resources on those situations with the greatest potential for adverse health effects (Mulhausen and Damiano, 1998). Currently, a vast range of screening tools exists that are intended to systematically address workplace chemical risks (Money, 2003). The COSHH Essentials system (Russell *et al.*, 1998; Maidment *et al.*, 1998; Garrod and Rajan, 2003) and the ECETOC TRA (ECETOC, 2004) are among the most prominent and accepted examples for chemical exposure. Comparable tools are also available for pharmaceutical active ingredients (Naumann *et al.*, 1996). Some of the tools (e.g. COSHH Essentials) have been primarily developed for providing assistance to small and medium sized enterprises (SME) with respect to workplace risk assessment and control, whereas others (e.g. ECETOC TRA) are specifically developed for the regulatory risk assessment process. Available screening models for chemical exposure have recently been reviewed in the context of guidance setting for REACH (http://ecb.jrc.it/home.php?contenu=/document/reach/rip-find-reports/rip-3.2-1-CSA-CSR).

The core requirements of any screening tool should be that it is simple, readily understood, and with an appropriate level of conservatism (Tielemans *et al.*, 2007). In general, one of the main weaknesses of the available screening tools is that only few have been properly validated. This prohibits a comprehensive evaluation and weighing of the available tools. Tools that are, at least to some extent, validated are COSHH Essentials (Tischer *et al.*, 2003; Jones and Nicas, 2006a, b; Money *et al.*, 2006), ECETOC TRA (ECETOC, 2004), and EASE (Bredendiek-Kämper, 2001; Cherrie and Hughson, 2005; Hughson and Cherrie, 2005; Creely *et al.*, 2005; Johnston *et al.*, 2005). In the near future, insight into accuracy of models should substantially grow in order to make transparent decisions concerning the selection of sound screening tools. This may also result in the selection of several complementary tools, each with a distinct validity domain.

In the Netherlands, the web-based tool called "Stoffenmanager" was initially developed to assist SMEs to prioritize and control risks of handling chemical products in their workplaces. The background and underlying assumptions of the Stoffenmanager are described by Marquart *et al.* (2007). The rationale of the underlying exposure algorithm is based on work of Cherrie *et al.* (1996; 1999) but is adapted in several ways. The model uses process information, physicochemical characteristics, and mass balances to give a relative ranking of exposure situations. To guarantee a sound risk assessment and further acceptance of the Stoffenmanager a comprehensive evaluation of its underlying exposure algorithm is highly warranted.

The aim of the present study was to explore the accuracy of the Stoffenmanager exposure algorithm. This was done by comparing its semi quantitative exposure rankings for specific substances with exposure measurements collected from several occupational settings to derive a quantitative exposure algorithm. Mixed effect models were used to evaluate the predictive value of Stoffenmanager scores and to quantify the level of uncertainty in the algorithm.

Materials and methods

Outline of Stoffenmanager exposure algorithm

The Stoffenmanager exposure algorithm has been described elsewhere by Marquart *et al.* (2007). For description of specific parameters and classes within parameters we refer to that paper. The exposure algorithm is based on a source-receptor approach developed by Cherrie *et al.* (1999) and incorporates modifying factors related to source emission and dispersion of contaminants. Most parameters are divided into classes with scores on a logarithmic scale, i.e. ranging from 0 through 0.03, 0.1, 0.3, 1, 3 to 10. These weighing factors can be derived from tables as described by Marquart *et al.* (2007). The volatility is the only parameter that is assumed to be linearly related to exposure and is expressed on a continuous scale. The total personal exposure score (C_t) is the sum of exposure levels due to near field (NF) sources (C_{nf}), far field (FF) sources (C_{ff}), and diffusive sources (C_{ds}), adjusted for possible use of control measures at the worker such as a control room (η_{imm}):

$$C_t = (C_{nf} + C_{ff} + C_{ds}) \cdot \eta_{imm} \qquad (1)$$

Exposure due to NF sources (C_{nf}) is a multiplicative function of type of handling of the product (H), intrinsic emission of the product (E), local control measures (η_{lc}), and general ventilation in combination with room size (η_{gv_nf}). A source is considered to be in the near field if it is located within 1 meter of the head of the worker; the FF comprises the remainder of the room. The scores for handling are related to a number of characteristics such as energy transfer by a process that causes a product to become airborne and the scale of use. Intrinsic emission is a parameter that relates to vapour pressure of liquids and dustiness of powders. The Stoffenmanager incorporates various local control measures such as containment of the source, local exhaust ventilation (LEV), and reduction of dust exposure due to wetting. Mixing and dilution of contaminants in workroom air is taken into account by general ventilation in conjunction with room size (Cherrie, 1999). Exposure due to NF sources is expressed as follows:

$$C_{nf} = E \cdot H \cdot \eta_{lc} \cdot \eta_{gv\_nf} \qquad (2)$$

Exposure due to FF sources (C_{ff}) is described according to a similar multiplicative function:

$$C_{ff} = E \cdot H \cdot \eta_{lc} \cdot \eta_{gv\_ff} \qquad (3)$$

Note that for the FF source, if present, the same intrinsic emission, handling and local control measures are assumed as for the NF source. The impact of general ventilation in combination with room size is different for NF and FF sources.

The diffusive source (C_{ds}) representing background concentration is expressed as follows:

$$C_{ds} = E \cdot a \qquad (4)$$

In this expression *a* represents a relative multiplier for potential of diffusive sources not captured by questions regarding the FF sources, depending on the regularity of inspections of machines and on the cleaning procedure in the work area. This represents exposure due to unpredictable sources such as spills or leaks.

The intrinsic emission for liquids is the only continuous parameter in the Stoffenmanager and is expressed as follows:

$$E = (P_i / 30.000) \cdot F_i \tag{5}$$

With P_i representing vapour pressure (Pascal) and F_i a factor equal to the weight fraction of substance i in a mixture. The relation between vapour pressure and exposure is assumed linear between 10 and 30.000 Pascal. All substances with a vapour pressure equal to or lower than 10 Pascal are assigned the same minimum score for P_i (i.e. 10/30.000), whereas substances with a vapour pressure equal to or higher than 30.000 Pascal are assigned the same maximum score for P_i (i.e. 30.000/30.000). In order to predict exposure to a group of substances (e.g., *n* volatile organic compounds or *n* isocyanates) we used the following intrinsic emission equation:

$$E = \sum_{i=1}^{n} (P_i / 30000) \cdot F_i \tag{6}$$

Collation of exposure data

Exposure data were collected using two strategies. First, we conducted 7 surveys specifically for validation of the Stoffenmanager. Sector and companies were selected from a network of industry participating in the VASt program. The VASt program is established by the Dutch Ministry of Social Affairs and Employment to assist small and medium enterprises (SMEs) in reinforcing the working condition policy on hazardous substances (http://vast.szw.nl). In total, 63 companies in 7 different sectors were recruited. All participating workers were experienced professionals who preformed their work as normal. For scenario's describing the handling of solids, we used inhalable dust measurements for comparison with Stoffenmanager scores. Respirable dust measurements were considered to be outside the scope of the presented validation study and should be dealt with in a later stage. Inhalable dust measurements were conducted in the animal feed industry, construction industry, textile industry, and bakeries and flour handling industry. Personal air measurements were obtained from a random sample of potentially exposed workers in the companies. The dust samples were collected using a portable pump with a flow rate of 2 l/min and a Teflon filter mounted in a PAS6 sampling head. Sampling was performed in the breathing zone of the worker for approximately 4 hours. Dust levels were determined by weighing the filter in a climate-controlled weighing room where the filters were conditioned for 24 hours prior to weighing. The limit of detection was assessed as the average weight difference of the blank filters plus three times the standard deviation.

For scenario's describing the handling of liquids, task-based measurements to solvents were conducted in auto body repair shops, printing industry, and metal industry. Inhalation exposure to solvents during a specific task was assessed by personal air sampling using an air sampling pump (flow rate of 250 ml/min) and charcoal adsorption tubes. Samples were transported to an external laboratory (RPS). After extraction with CS_2 the samples were analyzed on a broad range of organic solvents (approximately 250), using GC-FID.

Occupational hygienists conducted all surveys using a checklist to collect information in a structured way. Workers were followed throughout their measurement period and information on tasks performed was registered. This checklist allowed the hygienist to record frequency and duration of tasks conducted and the relevant Stoffenmanager parameters for each task. Information on substances and their concentrations in a mixture were retrieved from safety data sheets (SDS) available at the workplace. In those cases that the concentration was given in ranges the midpoint of the range was used in the analyses.

Secondly, occupational exposure data sets were collected from archives of TNO. These data originated from research projects funded by the Dutch Government in the past years. For details on the methodology we refer to the individual publications (Brouwer *et al.*, 2006; de Cock and van Drooge, 2002; de Jong *et al.* 1998; Links *et al.*, 2007; Links *et al.*, 2002; Marquart *et al.*, 1999; Preller and Schipper 1999; Pronk *et al.*, 2006; Vreede and Amelsfort, 1997; Vreede and Amelsfort, 1997; Vreede *et al.*, 1994). In addition a network of industry and occupational health services participating in the Dutch "VASt program" was used to collect more exposure data. In the context of this program a large number of research and consultancy projects has been conducted and funded (partly) by the Dutch Government. We used this momentum to collate exposure data. The data collection process was facilitated by a request for data on the "VASt" website. In addition, a specific newsletter concerning the evaluation study was sent to contact persons of various sectors and companies. Both task-based and shift-based exposure measurements were collected. All data reflect personal exposure measurements. Table 1 shows the number of measurements available from each data source and separate for handling of solids and liquids.

Evaluation of data quality and assignment of Stoffenmanager scores

Based on the contextual information assignment of Stoffenmanager scores was carried out by one occupational hygienist. Subsequently, these scores were reviewed by another occupational hygienist. Both occupational hygienists were involved in the development of the Stoffenmanager exposure algorithm. In case of inconsistencies between the two occupational hygienists the assessment was discussed until consensus was reached. Subsequently, a larger expert panel of 4 persons (including the initial 2 occupational hygienists) met to verify and discuss all potential inconsistencies with respect to assigning Stoffenmanager scores. This consensus meeting only occasionally resulted in modification of a Stoffenmanager score for a particular data point due to misinterpretation of contextual information during the initial assessment. The whole consensus procedure was conducted blind to the measurement results.

When multiple tasks were conducted during a measurement, Stoffenmanager scores (C_t) were calculated for each task and then combined together as a time-weighted summation for the tasks making up the measurement period. Multiple tasks were considered when identifiable differences existed in type of handling, product, controls or room during a particular measurement period.

Guidelines for data quality were applied to rank data into one of 3 categories: good, moderate or poor. Only good quality data were eventually used in the analyses. All exposure reports were reviewed to evaluate whether the work was undertaken competently and valid sampling and analytical techniques were used. In addition, exposure data were only labelled to be of good quality if required core information was documented (Rajan *et al.*, 1997; Tielemans *et al.*, 2002), if all Stoffenmanager parameters could be retrieved, and if time registration was accurate. These criteria were considered stringent and we rejected any data sets not meeting these criteria. Often an occupational hygienist had to make further enquiries with the original researchers to retrieve additional details with respect to Stoffenmanager parameters and help clarify any ambiguities.

Data processing and statistical analyses

Both the measured exposure data and contextual information to derive Stoffenmanager scores were collected in a relational database in Microsoft Access 2003. To safeguard confidentiality data were entered anonymously into the database. The data were analyzed using SAS statistical Software (version 9.1.3; SAS Institute, Cary, NC). Visual inspection of the measured concentrations for solid and liquid scenarios showed a log-normal rather than a normal distribution, so descriptive statistics are presented both as arithmetic and geometric mean levels with geometric standard deviation and range. In situations where measured values were below the limit of detection (LOD), 0.5 times the LOD was substituted for measured values (Hornung and Reed, 1990).

Spearman correlation coefficients were calculated to study the relation between Stoffenmanager scores and measured exposure concentrations. Mixed-effect regression models were used to further explore this relation by using the natural log of exposure data as dependent variable and the natural log of Stoffenmanger scores as independent variable, with random between- and within-company components of variance. Alternatively, a model with untransformed Stoffenmanager scores as independent variable was also tested but showed a poorer fit (statistically significant using likelihood ratio test). A compound symmetric covariance structure was used to model the data. The mixed model is given in equation 7, where Y_{ij} is the exposure level for the *i*-th company and the *j*-th worker; X_{ij} is the log-tranformed exposure level; β_0 is the intercept; β_1 represents the fixed effect of the log of Stoffenmanager scores; δ_i represents the random effect of the *i*-th company; and ε_{ij} represents the random effect of the *j*-th worker in the *i*-th company. It is assumed that δ_i and ε_{ij} values are normally distributed with mean equal to 0 and variance of σ^2_{bc} and σ^2_{wc}, respectively, representing the between- and within-company variability component.

$$Ln(Y_{ij}) = X_{ij} = \beta_0 + \beta_1 \cdot Ln(C_t) + \delta_i + \varepsilon_{ij} \qquad (7)$$

The mixed-effect regression models can be used to predict a geometric mean exposure level ($\hat{Y}$) for a given Stoffenmanager score C_t:

$$\hat{Y} = EXP\left[\beta_0 + \beta_1 \cdot Ln(C_t)\right] \tag{8}$$

The variation around the prediction is given by the components of variance. Hence, the random components of variance in conjunction with relevant z values of the standard normal distribution can be used to predict any cut point for a given Stoffenmanager score. For instance, to arrive at a conservative 90 percentile the prediction of the geometric mean should be multiplied using the following factor M:

$$M = EXP[1.28 \cdot \sqrt{\sigma_{bc}^2 + \sigma_{wc}^2}] \tag{9}$$

This factor M can be considered a so called 'uncertainty factor'.

Graphical analyses of residuals were performed to evaluate assumptions of homoscedasticity. Statistical analyses were conducted separately for scenario's covering the handling of solids and liquids. For liquids, more detailed analyses were performed for volatile and non-volatile substances. For solid scenarios, a stratified analysis was conducted for handling powders and granules (e.g., mixing, weighing) and comminution of solid materials (e.g., sawing, grinding). In addition, stratified analyses were conducted based on the type of data source: i.e., A) data collected in this study, B) data from previous TNO research projects funded by the Dutch Ministry of Social Affairs and Employment, and C) data collected in the context of the VASt program.

Results

The results presented in Table 2 show the wide range of 14 different industries with in total 378 measured exposure data ranging from 0.0004 to 420 mg/m^3 for inhalable dust scenarios. The data represent both short-term and long-term (shift) measurements. A relatively large number of inhalable dust measurements was available for handling powders (pyridoxine as a marker substance) in pharmacy shops (N = 78), flour dust among bakery workers (N = 56), dust among various construction sites (N = 74), wood dust in woodworking shops (N = 23), organic dust in the animal feed industry (N = 40), pigment powders in textile (N = 28) and paint industry (N = 20). Small data sets were available for the fertilizer industry (N = 6), dairy industry (N = 3), metal industry (N = 4), transhipment industry (N = 5), rubber industry (N = 4), and a publishing company (N = 1). One simulated workplace study was included focusing on the impact of dustiness of products on exposure levels using standard scenarios like scoping, weighing, and adding (N = 36).

The highest geometric mean dust exposure levels were found among measurements in the paint industry (GM = 31.9 mg/m^3; GSD = 4.26), the construction industry (GM = 14.0 mg/m^3; GSD = 3.02) the rubber/plastic industry (GM = 12.2 mg/m^3; GSD = 3.05), and the simulated workplace study (GM = 36.2 mg/m^3; GSD = 4.01). As expected, very low exposure levels were found among pharmacy workers (GM = 0.05 mg/m^3; GSD = 5.55).

Similar results are presented in Table 3 for the liquid scenarios (measuring solvents, pesticides/biocides or isocyanates) with in total 320 measured exposure data in different industries ranging from 0.0002 to 1,762 mg/m^3. The range in median sampling times across studies is large (9 - 510 minutes). Data in the agricultural setting represent application of pesticides in tree nurseries (Bitertanol; N = 19) and horticulture (Methomyl; N = 17). Data on biocide exposure were available for application of antifouling paint in boatyards (dichlofluanid, copper; N = 31) and pest control / disinfection operations (cyfluthrin, deltamethrin; N = 16, chlorpyrifos; N = 29, quaternary ammonium compounds; N = 14). Data on volatile organic compound exposure levels were collected for handling paint and degreasing activities in the car body repair industry (N = 15) and metal industry (N = 56), handling of printing inks (N = 7), and gluing in orthopaedic shoe manufacturing (N = 26). Isocyanate exposure (HDI oligomers) was measured among car body repair workers involved in mixing and spraying of paint and gun cleaning (N = 90).

The highest geometric mean solvent exposure levels (total volatile organic compounds) were found in the orthopaedic shoe manufacturing (GM = 128 mg/m^3; GSD = 3.50) and the metal industry (GM = 56.7 mg/m^3; GSD = 5.90). Activities with non-volatile substances (pesticides, biocides, isocyanates) resulted in much lower exposure levels.

Tables 4 and 5 describe the occurrence of key parameters for calculating the Stoffenmanager score for both solid (Table 4) and liquid scenarios (Table 5). For solid scenarios, tasks with handling scores > 0 covered about 81 percent of the total sampling time (= 66,386 minutes), and for liquid scenarios this appeared to be 66 percent of the total sampling time (= 29,264 minutes) across all measurements. This implies that in 81 and 66 percent of the time activities were conducted with at least some potential for exposure. In the remainder of the time activities were conducted in the far field (FF) and near field (NF) which were not related to relevant exposure (i.e., handling score equal to zero). In these time periods a diffusive source may still be present.

Stoffenmanager parameters of the NF and FF component were only reported for the sampling time with handling scores > 0. For solid scenarios, Table 4 shows that some parameter classes were not or only to a very limited extent covered by the exposure data: i.e., outside work, solids with very low intrinsic emission scores (i.e., firm granules or flakes), enclosure, LEV in combination with enclosure, and wetting. Other parameter classes were reasonably covered. For the handling parameter the exposure data were distributed as follows: 21.6 % in category 0.1, 25.7 % in category 0.3, 3.6 % in category 1, 20.4 % in category 3, and 28.7 % in category 10.

For liquid scenarios, Table 5 shows that the following parameters are not or only to a limited extent covered by the data: i.e., handling score 0.1, enclosure, and LEV in combination with enclosure. For the handling parameter the exposure data were distributed as follows: 0 % in category 0.1, 6.9 % in category 0.3, 24.5 % in category 1, 20.7 % in category 3, and 47.9 % in category 10.

The Spearman correlation coefficients between Stoffenmanager scores and measurements appeared to be good for handling solids ($r_s = 0.80$; N = 378; $P < 0.0001$) and liquid scenarios ($r_s = 0.83$; N = 320; $P < 0.0001$) (Table 6). However, the correlation for liquid scenarios appeared to be lower when calculated separately for sets of volatile substances with a vapour pressure > 10 Pa ($r_s = 0.56$; N=104; $P < 0.0001$) and non-volatile substances with a vapour pressure ≤ 10 Pa ($r_s = 0.53$; N = 216; $P < 0.0001$) (Table 6). Whether volatile substances were reported in milligrams per cubic metre (mg/m^3) or in parts per million (ppm) did not influence the correlation with the Stoffenmanager score. The dust scenarios could be subdivided into handling resulting in comminuting of bound products (e.g., sawing, grinding; N = 52) and handling of powders and granules (N = 326). The latter type of handling resulted in a correlation coefficient of 0.81, whereas activities leading to comminuting of bound products showed a lower correlation coefficient (0.41). Stratifying the data according to source did not show substantial differences in correlation coefficients: i.e. A) this study (solids: $r_s = 0.58$, N = 154, $P < 0.0001$; liquids $r_s = 0.58$, N = 78, $P < 0.0001$), B) previous research projects (solids: $r_s = 0.64$, N = 100, $P < 0.0001$; liquids $r_s = 0.53$, N = 216, $P < 0.0001$), C) VASt program (solids: $r_s = 0.75$, N = 124, $P < 0.0001$; liquids $r_s = 0.44$, N = 26, $P = 0.02$).

The further exploration of the data by using mixed effects models with a random company effect resulted in the models presented in Table 7. The relationship is graphically illustrated for handling of solids (Figure 1) and liquids (Figure 2). Both models had a statistically significant intercept (dust: $\beta_0 = 1.55$; standard error = 0.17 / liquids: $\beta_0 = 6.17$; standard error = 0.36). The slope of the regression line appeared to show a positive linear relation between the natural log of Stoffenmanager scores and natural log of measurement results for scenarios describing handling of solids ($\beta_1 = 0.69$; standard error = 0.05) and liquids ($\beta_1 = 0.87$; standard error = 0.04). These two regression equations enable the prediction of geometric mean exposures for a given Stoffenmanager score (C_t):

$$\hat{Y}_{solid} = EXP\left[1.55 + 0.69 \cdot Ln(C_t)\right]$$

$$\hat{Y}_{liquid} = EXP\left[6.17 + 0.87 \cdot Ln(C_t)\right]$$

Total variance appeared to be higher for the liquid scenarios ($\sigma^2_{\text{total}} = 4.43$) compared with the solid scenarios ($\sigma^2_{\text{total}} = 2.88$). Based on these variance components the difference between the predictions of the GM and the reasonable worst case (90th percentile) was estimated to be a factor 8.8 ($e^{(1.28 * \sqrt{(2.88)})}$) for solid scenarios and a factor 14.8 ($e^{(1.28 * \sqrt{(4.43)})}$) for liquid scenarios.

Discussion

Although the concept of validation has been recognized as an indispensable part of model development (Armstrong *et al.*, 1992; Schneider and Holst, 1996), only few validations of exposure models for risk assessment are described in the open literature (Tischer *et al.*, 2003; Jones and Nicas, 2006; ECETOC, 2004; Cherrie and Hughson, 2005; Hughson and Cherrie, 2005; Money *et al.*, 2006; Bredendiek-Kämper, 2001; Johnston *et al.*, 2005). The present study indicated that there is good agreement between Stoffenmanager scores and exposure measurements for both solid and liquid scenarios. The mixed effects regression models with natural logged Stoffenmanager score as independent parameter explained a substantial part of the total exposure variability (52% for solid scenarios and 76% for liquid scenarios). This proportion of explained variance is well in accordance with other, more specific exposure studies focusing on a particular industrial setting (Burstyn and Teschke, 1999). Hence, this performance increases our confidence in the use of the Stoffenmanager as a generic tool for risk assessment. Yet, a cross validation has to be conducted in order to evaluate the accuracy of the mixed effect models (Hornung, 1991). This cross validation using a small set of good quality exposure data will be conducted in a subsequent step (Schinkel *et al.*, in preparation).

Notwithstanding the good correlation and parameter estimates from the mixed effects model the data show substantial variability in exposure measurements given a certain Stoffenmanager score. It is likely that various sources of uncertainty are responsible for this observed variability. First, there is uncertainty in the information describing the input parameters. Some parameters were most likely estimated with substantial error. For instance, the fraction of a substance in a mixture is often indicated in very broad ranges (e.g. 25-50%) in the available SDS. Likewise, other factors at the workplace may be assessed with varying degrees of error. Although we applied rigid quality control criteria for inclusion of data this source of uncertainty undoubtedly resulted in discrepancies between model estimates and measurements.

Secondly, there is the usual degree of error inherent in the measurement data (Tielemans *et al.*, 2002). Hence, measurements do not reflect true exposure and are itself an 'alloyed gold standard' (Wacholder *et al.*, 1993). Uncertainty in the measurement data may be introduced by analytical error varying across laboratories or for instance differences in aerosol sampling instruments (Kenny *et al.*, 1997). We consider this to be a relatively unimportant source of uncertainty, as measurement error is generally believed to be minor as compared to true exposure variability (Nicas *et al.*, 1991). Stratified analyses did not reveal substantial differences in results between data sources, suggesting that uncertainty issues are not overrepresented in a particular data source.

A third, more fundamental reason for discrepancies between Stoffenmanager estimates and exposure measurements is model uncertainty (Morgan and Henrion, 1990). The Stoffenmanager exposure algorithm is to a large extent based on a well described conceptual model of Cherrie *et al.* (1996; 1999) with some modifications, i.e., the definition of intrinsic emission for liquid scenarios, assumptions with respect to the strength of FF sources (similar tasks and local controls are assumed as for NF sources), and the definition of background exposure due to diffusive sources. It is generally felt that the underlying concepts incorporate the critical determinants of exposure (Creely *et al.*, 2005). Yet, as exposure is influenced by so many aspects only the most dominant processes can be accounted for. For instance, one important aspect, personal behaviour, was explicitly not taken into account as this parameter is very difficult to characterize and quantify. Hence, there is scope for improvement by a further description of how workers become exposed (Tielemans *et al.*, 2008). Furthermore, the scaling of the individual parameters is an important area for additional research. A logarithmic scale is used for most variables. The scaling is based on expert judgement and should be evaluated again when more exposure data become available. Determinant analyses using a large exposure database may provide important new insights into proper parametization of individual variables of the Stoffenmanager.

Priority areas for further development of the Stoffenmanager are refinement of handling classes, inclusion of more options for control measures, and the provision of high quality guidance information for reliable classification. A large number of classes in handling and local control parameters is envisaged to achieve a more precise algorithm in the near future. For instance, at the very low end of the exposure range, such as well controlled activities in laboratories or pharmacies, one may consider the introduction of smaller handling scores than currently exist in Stoffenmanager. Similarly, there is scope for more differentiation in control efficacy values. These refinements require an expert elicitation procedure using a panel of multiple experts to reliably capture the current state of knowledge with respect to these parameters (Walker *et al.*, 2001).

An important issue related to model uncertainty is that the Stoffenmanager inherently assumes that exposure is linearly dependent on the fraction of a substance in a mixture. However, the evaporation of a substance is also dependent on the specific composition of the mixture and on the activity coefficient of each component reflecting molecular interactions (Nielsen and Olsen, 1995; Fehrenbacher and Hummel, 1996). In addition, one should ideally use the mole fraction of a substance in a mixture instead of a mass fraction to predict partial vapour pressure. In practice, however, there is only limited information on characteristics of the mixture available so that we had to rely on less adequate, but accessible information.

The model of Cherrie and colleagues has previously also been evaluated (Cherrie and Schneider, 1999; Semple *et al.*, 2001). The correlation coefficients found in their evaluation study are in accordance with or somewhat higher than the results presented in this paper. We found more scattering of exposure levels within a given Stoffenmanager score (i.e., "noise"). This discrepancy may well be explained by the fact that the methodology of Cherrie and colleagues was tailored to the specific assessment situation. Specific guidance material also included range-finding exposure data to calibrate the assessor. This is likely to help improve the accuracy and reliability of estimates (Hawkins and Evans 1989; Post *et al.* 1991). In contrast, a flexible approach with additional guidance for each specific situation is impossible for the generic version of the Stoffenmanager. However, branch-specific versions of the Stoffenmanager may be more accurate and reliable than the generic version.

The mixed effects regression models presented in this paper may be used for assessment of typical and so called reasonable worst case (RWC) exposures. The assessment can be based upon an appropriate percentile from the log-normal distribution as determined by the random components of variance. The technical guidance document (TGD) for risk assessment of new and existing substances currently recommends the 50th percentile for typical exposure and the 90th percentile for RWC exposure (ECB, 2003). However, these recommendations are not necessarily relevant for use of the Stoffenmanager. The TGD recommendations relate to measured data sets in rather broad exposure scenarios (e.g. "spray painting with solvent based paints"). Stoffenmanager scenarios can be defined much more specifically. Therefore, if conservative Stoffenmanager inputs are used to describe a scenario, we recommend using the 75th percentile as the estimator of the reasonable worst case exposure level. If more average Stoffenmanager inputs are used for parameters that vary within a broad scenario, such as room size and local controls, the 90th percentile would be preferred as estimator of the reasonable worst case.

As the scatter of exposure measurements for a given Stoffenmanager score is rather large, the differences between 50th and 90th percentile is a factor up to 8.8 for solid and 14.8 for liquid scenario's, respectively. For the 75th percentile a factor up to 3.1 (solids) and 4.1 (liquids) should be applied. These factors can be considered "safety factors" to incorporate model uncertainty and inherent exposure variability in the risk assessment process. However, more exposure data are needed in the future to properly investigate the stability of variance across the whole range of Stoffenmanager scores. Several authors have highlighted the relevance of heterogeneity of variance across fixed effects (van Tongeren *et al.* 2006; Friesen *et al.*, 2006).

The unexplained variability (i.e. uncertainty) might be reduced by further optimization of the conceptual model and refinement of parameters in the future (see discussion above). Yet, an additional strategy will be to combine the model estimates with available measurements relevant for the particular assessment scenario. Such an alternative strategy using Bayesian techniques to update model results with exposure data is proposed by Creely *et al.* (2005) and elaborated on by Tielemans *et al.* (2007). A few applications of a Bayesian approach to exposure assessment have already been described (Ramachandran *et al*, 1999, 2003; Hewett *et al.*, 2006). As random between-company exposure variability in the mixed-effect models is large there is potential for substantial improvement of Stoffenmanager estimates using site-specific data, even if only few measurements are available. We are currently exploring the possibilities of Bayesian techniques to update Stoffenmanager predictions.

The Stoffenmanager scores were derived by one assessor and these results were reviewed by a larger group using a consensus procedure. The consensus process is recommended by others as it helps to control for and resolve differences among experts as they gain knowledge from each other (Seel *et al.* 2007). There was good concordance among the experts in the consensus procedure. Yet, in our consensus procedure we did not look explicitly at the reliability of the algorithm. Some comparable methods have been evaluated and show good inter-rater agreement (Semple *et al.*, 2001; van Wendel de

Joode *et al.*, 2005). Most parameters in the Stoffenmanager algorithm are not prone to subjective interpretation and simply require an objective description of the situation (e.g., LEV is present or not; a subjective assessment of efficacy of LEV is not required). However, two parameters provide the opportunity for subjective judgement: i.e., handling parameter and intrinsic emission for solids (dustiness). This potential for inconsistent interpretations was reduced as much as possible by providing transparent descriptions and by giving various examples for each parameter class. Nevertheless, a reliability study focusing on these aspects should be conducted in the near future.

Although the collated exposure data cover a wide range of situations, not all Stoffenmanager parameter combinations are included in the validation dataset. For solid scenarios, not all intrinsic emission scores are well represented; e.g. substances with very low dustiness potential are not covered by the data. In addition, a very limited number of measurements in the dataset were conducted outside. Likewise, completely contained and controlled process conditions (e.g. glove boxes) as well as wet suppression techniques were not included in the data. Hence, the performance of the model for these situations is not properly described in this study. Occupational activities such as processing of melted or burning materials (e.g., hot moulding, calendaring) or hot work techniques (e.g. welding, soldering) are lacking in the data set. In addition, only inhalable dust measurements are used in the validation study and thus the predictive value of the algorithm for respirable dust could not be assessed. Hence, these types of activities and exposures are currently outside the validity domain of the Stoffenmanager algorithm and should be dealt with in a later stage.

In general, we believe it is important to regularly update validation and calibration of exposure models as workplace scenario's, exposure levels, and relations between determinants and exposure will change over time (Kromhout and Vermeulen, 2000; Creely *et al.*, 2007). Currently, a web-based exposure database containing relevant contextual information is under development in the Netherlands (STEAMbase: SToffenmanager Exposure And Modelling database). The analyses described in this paper will be expanded when more good quality data become available in STEAMbase. In addition, new data will be used to re-examine the scaling of individual Stoffenmanager parameters. Such a cycle of regular model refinement and subsequent validation guarantees a method tailored to current work environments and process conditions. A larger number of measurements may also facilitate development of separate mixed effects models for scenarios with different exposure mechanisms: e.g., handling of volatile substances (vapour exposure) and non-volatile substances (aerosol exposure).

In conclusion, Stoffenmanager appears to be a promising generic tool for exposure assessment. The Stoffenmanager is increasingly used as a tool to support SME in The Netherlands. This study shows that Stoffenmanager may also be used as a quantitative model. The mixed effect models provide an explicit treatment of uncertainty and definition of so called 'uncertainty factors'. Several refinements in model parameters are planned for the near future. The link between Stoffenmanager and STEAMbase will hopefully result in a gradual increase of data available for calibration of the model.

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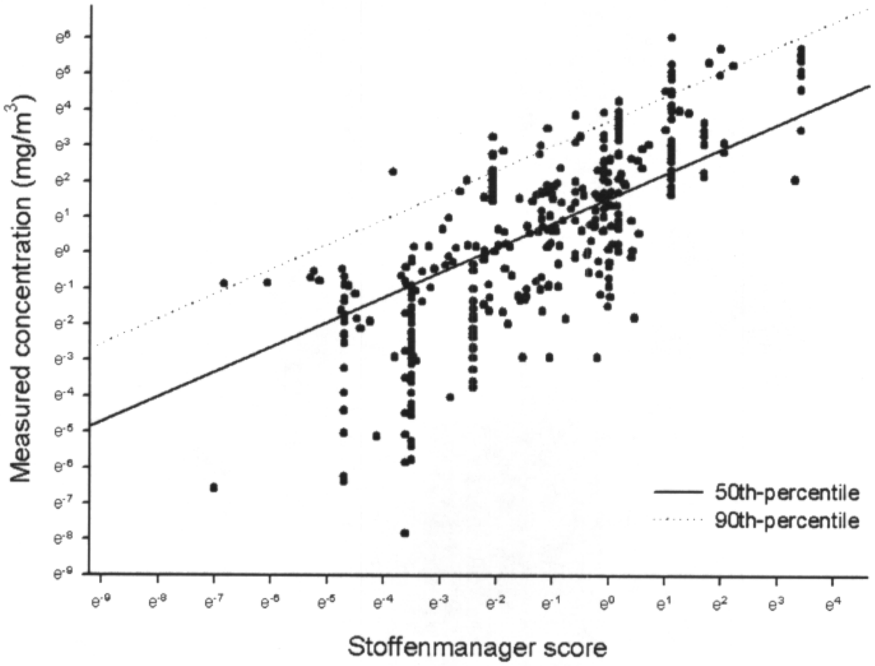
Capture for figures

Figure 1. Association between Stoffenmanager scores and measured inhalable exposure concentrations (mg/m^3) for handling of solids

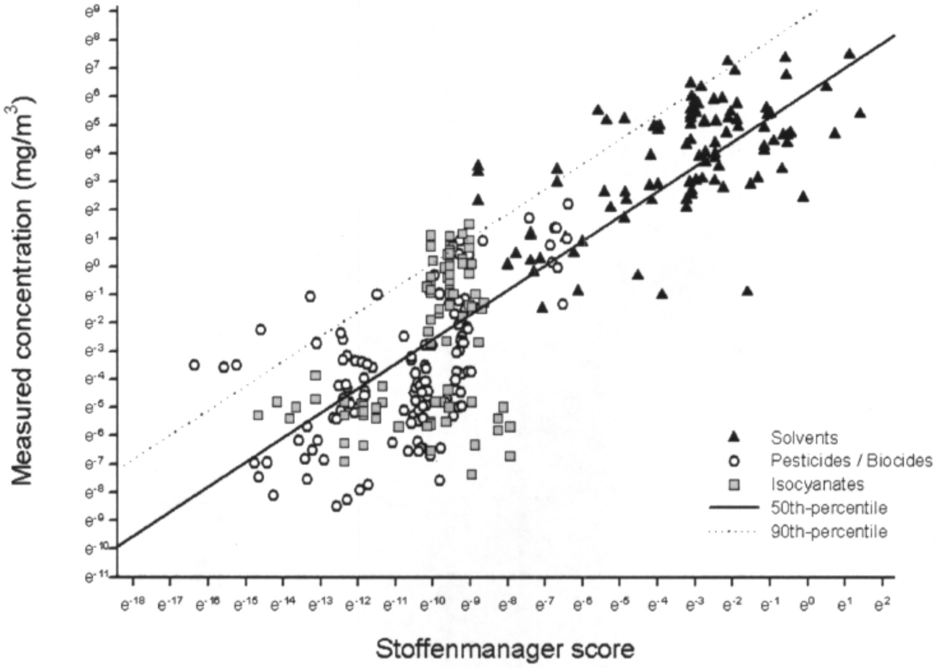
Figure 2. Association between Stoffenmanager scores and measured inhalable exposure concentrations (mg/m^3) for liquid scenarios

Figure 1.



Measured concentration (mg/m^3)
e^6
e^5
e^4
e^3
e^2
e^1
e^0
e^{-1}
e^{-2}
e^{-3}
e^{-4}
e^{-5}
e^{-6}
e^{-7}
e^{-8}
e^{-9}
e^{-9}
e^{-8}
e^{-7}
e^{-6}
e^{-5}
e^{-4}
e^{-3}
e^{-2}
e^{-1}
e^0
e^1
e^2
e^3
e^4
Stoffenmanager score
50th-percentile
90th-percentile

Figure 2.



Measured concentration (mg/m³)
e⁹
e⁸
e⁷
e⁶
e⁵
e⁴
e³
e²
e¹
e⁰
e⁻¹
e⁻²
e⁻³
e⁻⁴
e⁻⁵
e⁻⁶
e⁻⁷
e⁻⁸
e⁻⁹
e⁻¹⁰
e⁻¹¹
e⁻¹⁸
e⁻¹⁷
e⁻¹⁶
e⁻¹⁵
e⁻¹⁴
e⁻¹³
e⁻¹²
e⁻¹¹
e⁻¹⁰
e⁻⁹
e⁻⁸
e⁻⁷
e⁻⁶
e⁻⁵
e⁻⁴
e⁻³
e⁻²
e⁻¹
e⁰
e¹
e²
Stoffenmanager score
▲ Solvents
○ Pesticides / Biocides
▨ Isocyanates
50th-percentile
90th-percentile

Table 1. Overview of number of exposure measurements available for each data source.

	Solids	Liquids
This study (A)	154	78
Previous research projects (B)	100	216
VASt program (C)	124	26

Table 2. Descriptive statistics of available measured exposure data for inhalable dust scenarios.

Type of industry/study	Source*	N	K	Median sampling time (min)	AM (mg/m^3)	GM (mg/m^3)	GSD	Range (mg/m^3)
Pharmacies	C	78	9	14	0.17	0.05	5.55	0.0004 - 2.63
Bakeries	A	56	17	382	2.75	1.31	3.18	0.05 - 48.0
Construction industry	A / B	74	20	230	28.4	14.0	3.02	1.31 - 310
Experimental study	B	36	1	15	84.3	36.2	4.01	5.22 - 313
Woodworking industry	C	23	5	250	2.18	1.27	3.11	0.20 - 7.20
Fertilizer industry	C	6	1	465	1.76	1.16	2.70	0.42 - 5.12
Dairy industry	C	3	1	391	1.00	0.73	2.85	0.24 - 1.92
Animalfeed industry	A	40	4	248	4.53	1.62	4.10	0.18 - 54.5
Metal industry	C	4	3	199	32.3	7.99	10.0	0.74 - 94.6
Transhipment industry	C	5	2	301	11.3	7.97	3.11	1.20 - 21.3
Rubber/plastic industry	C	4	1	147	19.4	12.2	3.05	3.50 - 51.8
Textile industry	A	28	6	233	0.50	0.25	3.04	0.06 - 4.82
Publishing company	C	1	1	447	0.53	0.53	-	-
Paint industry	B	20	10	53	74.3	31.9	4.26	1.90 - 420

N = Number of samples; K = Number of companies; AM = Arithmetic mean; GM = Geometric mean; GSD = Geometric standard deviation.

* See Table 1 for description of sources A, B, C.

Table 3. Descriptive statistics of available measured exposure data for liquid scenarios.

Type of industry	Substance	Source[*]	N	K	Median sampling time (min)	AM (mg/m^3)	GM (mg/m^3)	GSD	Range (mg/m^3)
Pest control/disinfection	Biocides (deltamethrin and (β)-cyfluthrin)	B	16	9	92	0.03	0.003	6.66	0.0003 – 0.34
	Biocides (chlopyrifos)	B	29	1	61	0.03	0.02	2.64	0.004 – 0.21
	Biocides (alkyldimethylbenzyl-ammoniumchloride)	B	14	10	32	0.09	0.05	2.93	0.01 – 0.42
Boatyards (antifouling paint)	Biocides (copper, dichlofluanid)	B	31	8	70	1.32	0.38	6.29	0.007 - 9.03
Agriculture	Pesticides (bitertanol)	B	19	9	41	0.004	0.003	2.43	0.0005 – 0.01
	Pesticides (methomyl)	B	17	17	69	0.01	0.004	5.14	0.0002 – 0.03
Car body repair shops	Isocyanates (total HDI oligomers)	B	90	17	9	0.58	0.08	13.6	0.0006 - 4.52
	Organic solvents (total volatile organic compounds)	A	15	8	10	59.3	4.67	9.98	0.36 - 563
Metal industry	Organic solvents (total volatile organic compounds)	A	56	14	24	175	56.7	5.90	1.06 – 1,572
Orthopaedic shoe manufacturing	Organic solvents (total volatile organic compounds)	C	26	10	510	257	128	3.50	10.4 - 1,762
Silkscreen printing industry	Organic solvents (total volatile organic compounds)	A	7	2	293	8.84	4.72	5.00	0.23 - 17.2

N = Number of samples; K = Number of companies; AM = Arithmetic mean; GM = Geometric mean; GSD = Geometric standard deviation

[*] See Table 1 for description of source A, B, C.

Table 4. Descriptive statistics of Stoffenmanager parameters for solid scenario's (378 measurements).

	Minutes**	%
Total task time with exposure (handling score > 0)	53500	100%
Ventilation		
General ventilation present	43734	81.7%
General ventilation absent	9766	18.3%
Room size		
< 100 m^3	9571	17.9%
100 – 1000 m^3	21091	39.4%
> 1000 m^3	21286	39.8%
Outside	1552	2.9%
Intrinsic emission score*		
0.1	0	0.0%
0.3	2909	5.4%
1.0	4616	8.6%
3.0	43205	80.8%
10	2770	5.2%
Handling score*		
0.1	11580	21.6%
0.3	13749	25.7%
1.0	1924	3.6%
3.0	10916	20.4%
10	15331	28.7%
Local controls		
None (score = 1)	41795	78.1%
LEV (score = 0.3)	11113	20.8%
Enclosure (score = 0.3)	15	0.03%
LEV and enclosure (score = 0.03)	577	1.1%
Wetting (score = 0.3)	0	0.0%
Near Field exposure source		
Present	48795	91.2%
Absent	4705	8.8%
Far Field exposure source		
Present	29583	55.3%
Absent	23917	44.7%

* Scores indicate the exposure potential: 0.1 (low) to 10 (high) (see Marquart et al., 2007).

** Sum of time periods across measurements.

Table 5. Descriptive statistics of Stoffenmanager parameters for liquid scenario's (320 measurements).

	Minutes**	%
Total task time with exposure (handling score > 0)	19218	100%
Ventilation		
General ventilation present	12163	63.3%
General ventilation absent	6294	32.8%
Spray cabin	761	4.0%
Room size		
< 100 m^3	3268	17.0%
100 – 1000 m^3	6383	33.2%
> 1000 m^3	8707	45.3%
Outside	860	4.5%
Handling score*		
0.1	0	0.0%
0.3	1329	6.9%
1.0	4709	24.5%
3.0	3983	20.7%
10	9197	47.9%
Local controls		
None (score = 1)	13057	67.9%
LEV (score = 0.3)	5868	30.5%
Enclosure (score = 0.3)	25	0.1%
LEV and enclosure (score = 0.03)	268	1.4%
Near Field exposure source		
Present	17824	92.7%
Absent	1394	7.3%
Far Field exposure source		
Present	13923	72.4%
Absent	5295	27.6%

* Scores indicate the exposure potential: 0.1 (low) to 10 (high) (see Marquart et al., 2007).

** Sum of time periods across measurements.

Table 6. Spearman correlation between Stoffenmanager scores and measured exposure concentrations (mg/m^3).

Scenario	N	r_s	P-value
Handling of solids	378	0.80	<0.0001
Handling resulting in comminuting	52	0.41	0.003
Handling of powders and granules	326	0.81	<0.0001
Handling of liquids	320	0.83	<0.0001
Volatile substances*	104	0.56	<0.0001
Non-volatile substances**	216	0.53	<0.0001

N = Number of measurements; r_s = Spearman correlation coefficient

* Including all substances with vapour pressure > 10 Pa (organic solvents)

** Including all substances with vapour pressure ≤ 10 Pa (isocyanates, biocides, pesticides)

Table 7. Mixed-effects regression models with the natural log of Stoffenmanager scores as fixed effect and random between- and within-company components of variance.

	Solids		Liquids	
	Estimate	SE	Estimate	SE
Intercept (β_0)	1.55	0.17	6.17	0.36
Stoffenmanager score (β_1)	0.69	0.05	0.87	0.04
Components of variance:				
Between-company (σ^2_{bc})	1.65	0.34	1.42	0.41
Within-company (σ^2_{wc})	1.23	0.10	3.01	0.29
Explained variance	52%		76%	

Table 1. Scores for intrinsic emission of solids

Intrinsic emission parameter	**Explanation**	**Score**
Solid objects	Solid forms of substances or products, such as blocks, kegs or slabs	0
Firm granules or flakes	E.g. firm polymer granules, granules covered with a layer of wax, bound fibers, such as in cotton. No dust emission without intentional breakage of the product	0.01
Granules or flakes	Granules of flakes that may fall apart and crumble. E.g. washing powder, sugar or fertilizer	0.03
Coarse dust	A dust cloud is formed, but settles quickly due to gravity. E.g. sand, coarse carbon black, calcium stearate, unbound fibres	0.1
Fine dust	A dust cloud is formed that is clearly visible for some time. E.g. talcum powder, flour	0.3
Extremely dusty products	A visible dust cloud remains airborne for a long time	1

Table 2a. Scores for handling of liquids

Description	Examples	Score
Handling of liquids in tightly closed containers	○ Transport/shifting of closed containers	0
Handling of liquids where only small amounts of product may be released.	○ Measuring doses using a dose-measuring device ○ Handling of small quantities in laboratory situations, like using pipettes	0.1
Handling of liquids at small surfaces or incidental handling of liquids	○ Gluing of stickers and labels ○ Cleaning of small objects like knives, ○ Cementing ○ (Un)coupling of tank lorries or (dis)connecting of production lines	0.3
Handling of liquids using low pressure, low speed and on medium-sized surfaces	○ Mixing/diluting of liquids by stirring ○ Manually drawing off or pouring of product ○ Painting of casings using a roller or brush ○ Gluing larger pieces together, e.g. shoe soles ○ Degreasing or cleaning small machines/tools/work pieces/tanks, etc. ○ Immersion of small objects in bucket with cleaning agent	1
Handling of liquids on large surfaces or large work pieces	○ Painting of walls or ships with a roller or brush ○ Degreasing of large machinery ○ Glueing or cleaning of floors ○ Handling of heavily contaminated tools/objects or packages ○ Handling of immersed objects, handling of painted objects ○ Mechanically immersing of large objects in an immersion bath for example for cleaning purposes	3
Handling of liquids (using low pressure but high speed) without creating a mist or spray/haze	○ Foaming a product for cleaning or coating purposes ○ Mixing of products under high velocity using a mixer ○ Uncontrolled pouring of a liquid from a large height, for example pouring of production flows ○ Use of metalworking fluids like lubricants during cutting, sanding or drilling activities.	3
Handling of liquids at high pressure resulting in substantial generation of mist or spray/haze	○ Spraying of product (using high-pressure or spray painting) ○ Fogging a product producing a visible mist ○ Opening a (pressurized) production line for taking samples, or opening a closed cleaning device to remove cleaned objects ○ Opening of a closed system where products are treated/present at high temperature or pressure ○ Activities in the direct vicinity of open baths (high process temperature, cooking liquid)	10

Table 2b. Scores for handling of solids

Description	Examples	Score
Handling of products in closed containers	○ Transport/shifting of barrels or plastic bags	0
Handling of product in very small amounts or in situations where release is highly unlikely	○ Shifting of packages of which the seams aren't dustproof ○ Weighing a few grams of product	0.1
Handling of product in small amounts or in situations where only low quantities of product are likely to be released	○ Moving of polluted/dirty packages ○ Weighing several hundreds of grams of product ○ Shifting of cement bags or sackcloth bags with product with a fork-lift truck ○ Kneading of paste	0.3
Handling of product with low speed or with little force in medium quantities	○ Producing cement wet mortar using a chip ○ Producing cement manually with a shovel ○ Handling small or light materials externally contaminated with a substance (for example collecting and piling up of cement bags) ○ Manual weighing of kilogram amounts of products for recipes (for example in the animal feeds or textile industries)	1
Handling of products or treatment of objects with a relatively high speed/force which may lead to some dispersion of dust	○ Manual dumping, relatively small scale ○ Manually scattering/strewing of the product ○ Sweeping a floor ○ Mixing of products with a mixer ○ Dumping of powders with a pipe ○ Manually scooping of products (high control level) ○ Manually handling of treated or contaminated products/materials (for example rubber parts are treated with anti-stick powder) ○ Manual sawing, boring, sanding, polishing, etc.	3
Handling of products or treatment of objects, where due to high pressure, speed or high force, large quantities of dust are generated and dispersed	○ Spraying of powders (powder coating) ○ Dumping of product from big bags ○ Bagging of product ○ Dumping of bags, large scale ○ Cleaning of contaminated machines or objects with compressed air ○ Machine sawing, boring, sanding, polishing, etc.	10

Table 3. Scores for local controls

Criteria	**Explanation**	**Score**
Containment of the source with local exhaust ventilation	Containment of the source in combination with local exhaust ventilation, e.g. a fume cupboard	0.03
Containment of the source	The source is fully contained, however no local exhaust ventilation is used within the containment	0.3
Local exhaust ventilation	Removal of air at the source of the emission. The dangerous substances are captured by an air stream leading them into a hood and duct system	0.3
Use of a product that limits the emission	E.g. wetting a powder, spraying of water	0.3
No control measures at the source		1

Table 4a. Scores for reduction by general ventilation for near-field sources, dependent on room size

Room size (volume)	**No general ventilation**	**Mechanical/natural ventilation**	**Spraying booth**
Volume < 100 m^3	10	3	0.1
Volume 100-1000 m^3	3	1	0.3
Volume >1000 m^3	1	1	1
Work is done outside	-	1	-

Table 4b. Scores for reduction by general ventilation for far-field sources, dependent on room size

	No general ventilation	**Mechanical/natural ventilation**	**Spraying booth**1)
Volume < 100 m^3	10	3	0
Volume 100-1000 m^3	1	0.3	0
Volume >1000 m^3	0.3	0.1	0
Work is done outside	-	0.1	-

1) When tasks are performed inside spray cabins it was decided that exposure due to a far-field source was unlikely

Table 5. Scores for the multiplier for the relative influence of background sources

	No daily cleaning	**Daily cleaning**
No regular inspections and maintenance of machines and equipment	0.03	0.01
Regular inspections and maintenance of machines and equipment	0.01	0

Table 6. Scores for reduction of immission

Score	**Reduction of immission parameter**	**Explanation**
0.03	The worker is in a separated (control) room with independent clean air supply	The workplace of the worker is in a (control) room that is equipped with an air supply independent of the air in the room where the source is
0.1	The worker works in a cabin without specific ventilation system	For example in a cabin of a tractor or truck, a cabin not equipped with filters, overpressure system etc. or behind a screen.
1	The worker does not work in a cabin	The employee is not protected from the source by using a cabin.

Table 7. Scores for protection by PPE

score	**Type**
1.00	none
	Dusts
0.40	Filter mask P2 (FFP2)
0.20	Filter mask P3 (FFP3)
0.40	Half mask respirator with filter, type P2L
0.20	Half mask respirator with filter, type P3L
0.20	Full face respirator with filter, type P2L
0.10	Full face respirator with filter, type P3L
0.20	Half/full face powered air respirator TMP1 (particulate cartridge)
0.10	Half/full face powered air respirator TMP2 (particulate cartridge)
0.10	Half/full face powered air respirator TMP3 (particulate cartridge)
0.05	Full face powered air respirator TMP3 (particulate cartridge)
0.20	Hood or helmet with supplied air system TH1
0.10	Hood or helmet with supplied air system TH2
0.05	Hood or helmet with supplied air system TH3
	Gases/Vapours
0.40	Half mask respirator with filter/cartridge (gas cartridge)
0.20	Full face respirator with filter/cartridge (gas cartridge)
0.20	Half/full face powered air respirator TM1 (gas cartridge)
0.10	Half/full face powered air respirator TMP2 or 3 (gas cartridge)
0.20	Hood or helmet with supplied air system TH1
0.10	Hood or helmet with supplied air system TH2
0.05	Hood or helmet with supplied air system TH3

Table 8. Scores for duration of exposure

Score[1)]	**Parameter**
0.06	1 to 30 minutes a day
0.25	0.5 to 2 hours a day
0.50	2 to 4 hours a day
1.00	4 to 8 hours a day

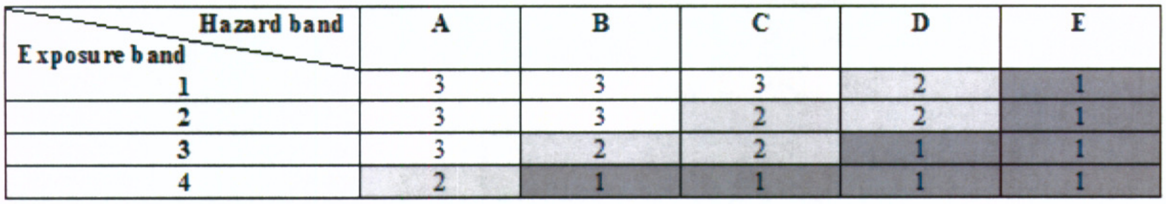
Table 9. Scores for frequency of exposure

Parameter	**Score**(1)
1 day a year	0.01
1 day a month	0.05
1 day per 2 weeks	0.10
1 day a week	0.20
2-3 days a week	0.60
4-5 days a week	1.00

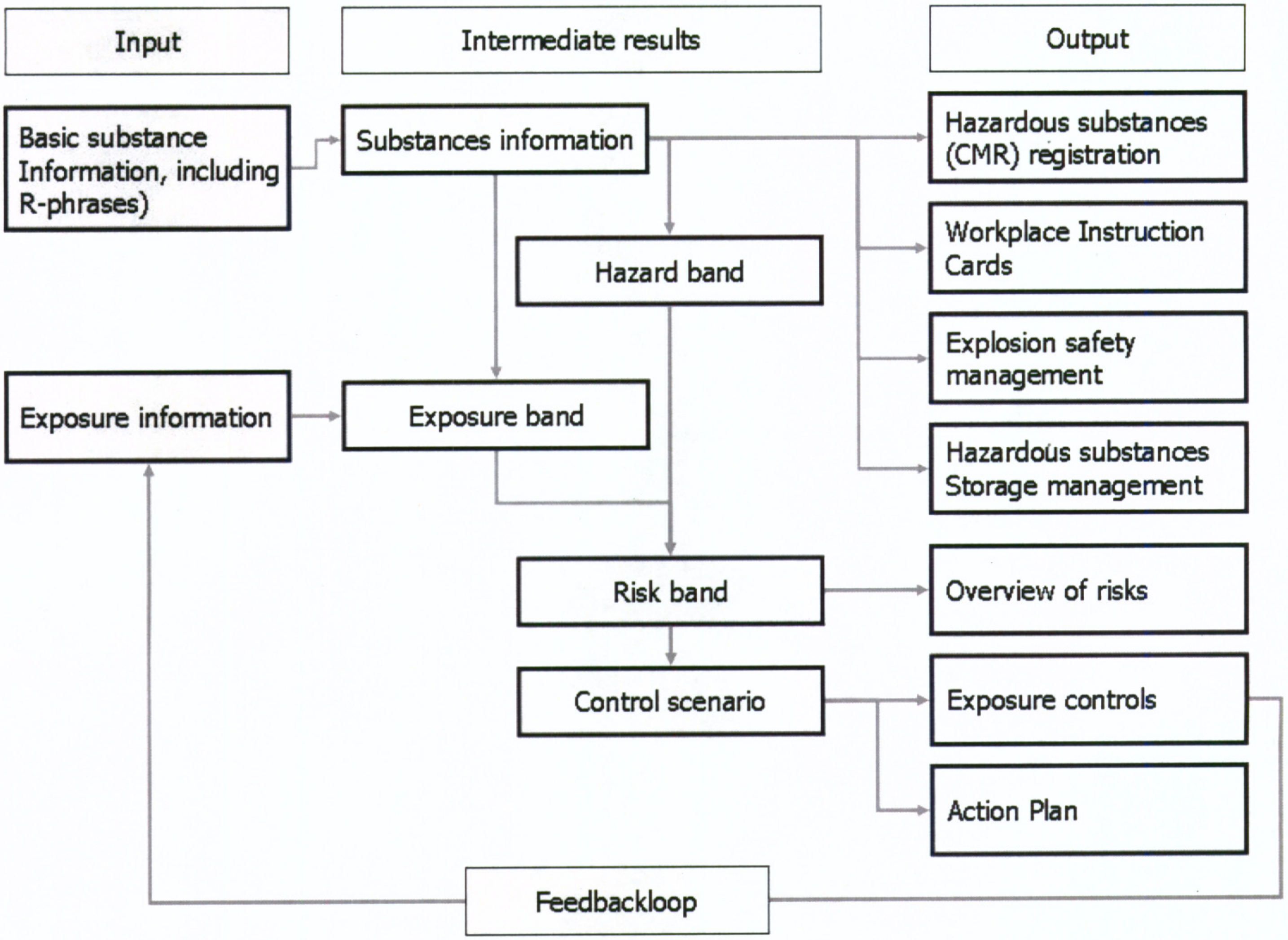
(1) a combination of unrealistic combinations of duration and frequency, e.g. "more than 4 hours per day" combined with "Two to four times per day" will be noted by the tool and the user will be asked to specifically confirm that this is indeed the combination that needs to be used.

Table 10. Assignment of exposure scores to exposure bands

Exposure band	Minimum exposure score	Maximum exposure score
1	0	0.00002
2	0.00002	0.002
3	0.002	0.2
4	0.2	20



Hazard band Exposure band	A	B	C	D	E
1	3	3	3	2	1
2	3	3	2	2	1
3	3	2	2	1	1
4	2	1	1	1	1


Input
Intermediate results
Output
Basic substance Information, including R-phrases)
Substances information
Hazardous substances (CMR) registration
Workplace Instruction Cards
Hazard band
Explosion safety management
Exposure information
Exposure band
Hazardous substances Storage management
Risk band
Overview of risks
Control scenario
Exposure controls
Action Plan
Feedbackloop