



NEG under SCOEL and REACH

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- NEG today
- Network & collaboration
- OEL setting procedures
- REACH and OELs
- Strengths of NEG
- NEG future

Outline

Nordic Expert Group

for Criteria Documentation of Health Risks from Chemicals

- **Task** Produce criteria documents as scientific basis for OEL setting by each Nordic country
- **Formed 1977**
- **Funding**
 - Nordic Council of Ministers (yearly funding until 2006)
 - Swedish Work Environment Authority
 - Norwegian government
- **Experts from Nordic institutes**
- **Secretariat**
 - in Stockholm, Sweden
- **www.nordicexpertgroup.org**
 - all documents can be downloaded (>170)

NEG today

English Danish Finnish Norwegian Swedish

Home

The Nordic Expert Group

Publications

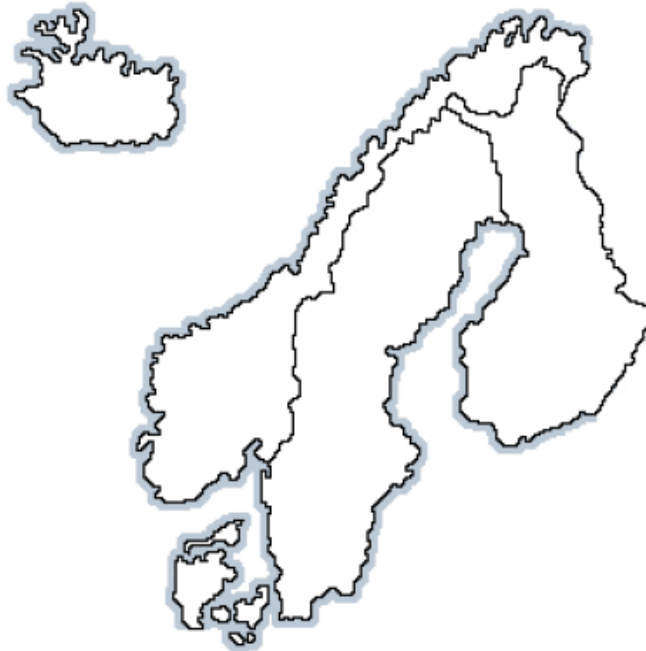
Ongoing projects

Author instructions

Links

Contact

Welcome to NEG



The Nordic Expert Group - a Nordic collaboration for production of criteria documents on chemicals for occupational exposure limits.

First international course on Chemical hazards at the workplace - Occupational exposure limits and implications

18 - 22 August 2008, Sweden

[View document](#)

NEG 30 years anniversary seminar

NEG 30 years anniversary seminar at the Nordic Work Environment Meeting (NAM) 24-27 August 2008, Norway.

[View programme](#)

Fungal spores

New criteria document on fungal spores.

[View document](#)

Microbial volatile organic compounds (MVOCs)

New criteria document on Microbial volatile organic compounds (MVOCs).

[View document](#)

www.nordicexpertgroup.org

From "simple" chemicals to complex groups, mixtures & issues

- **Penicillins**
- **Cyclic acid anhydrides**
- **Microbial VOCs**
- **Fungal spores**
- Inorganic acids
- Anesthetic gases (desflurane, isoflurane, sevoflurane)
- Occupational exposure to chemicals and hearing impairment
- Organophosphate esters
- Second-hand smoke
- PCBs
- Halogens
- Unusual working hours and implications in risk assessment of chemicals ?
- Silicon carbide production?
- Tunnel work ?

NEG today

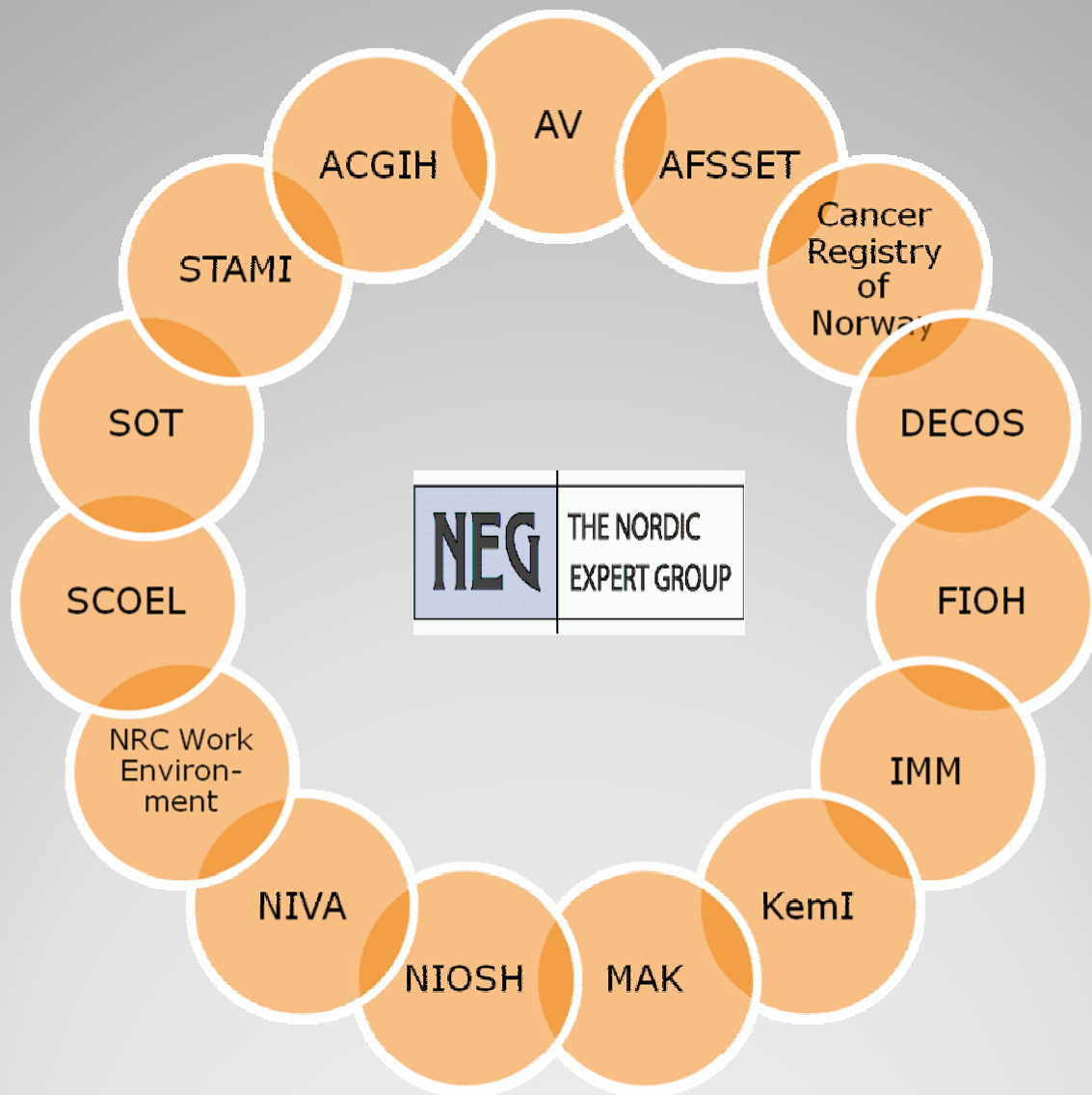
Target groups

- Nordic regulatory authorities
- International organisations: EU-SCOEL, WHO-IPCS
- National/regional authorities & organisations
- OSH services, toxicologists, researchers etc

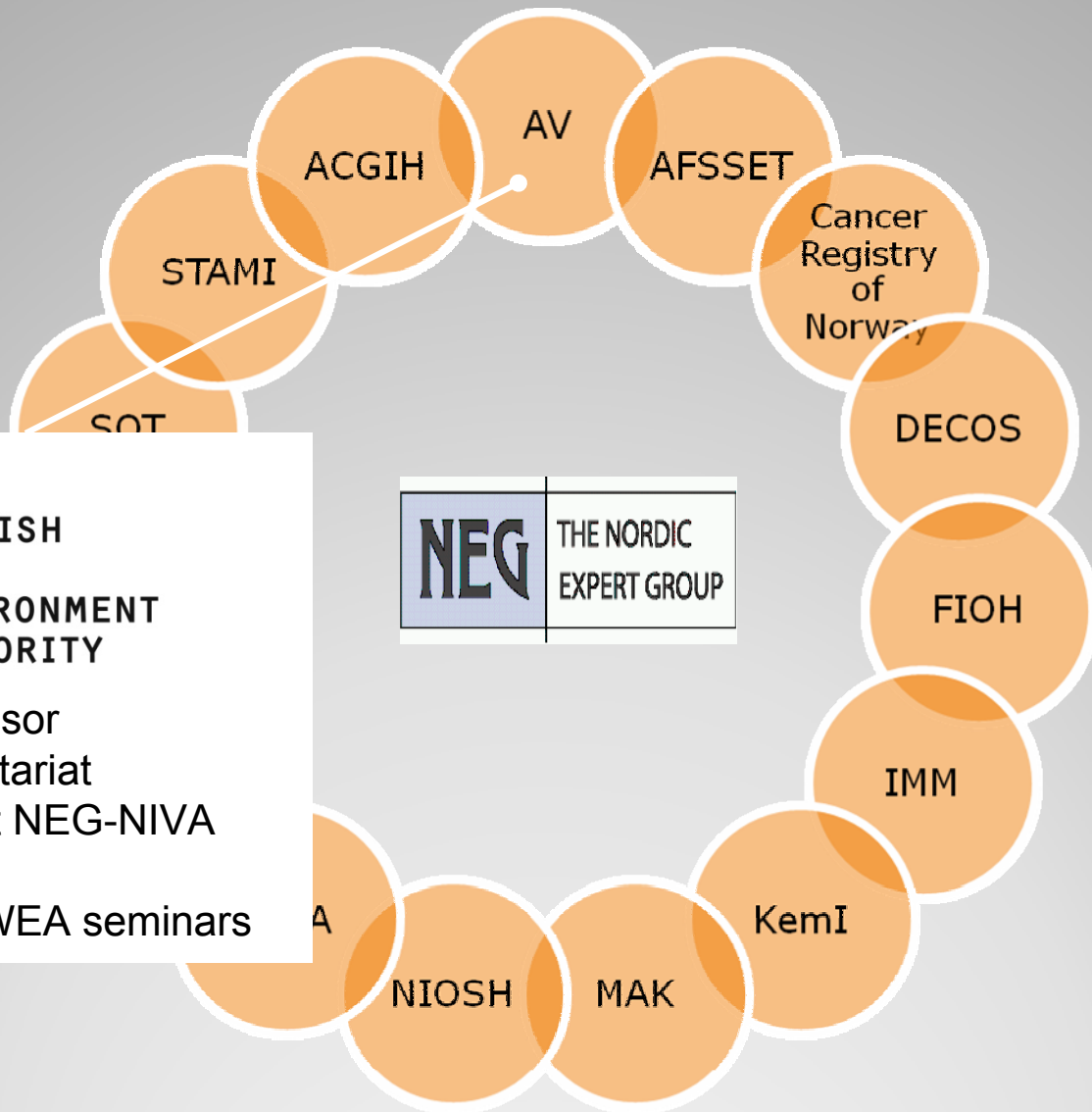
Why Nordic ?

- Stimulate internordic collaboration
- Uniform approaches and values
- Avoid duplicate work

NEG today



Network & collaboration

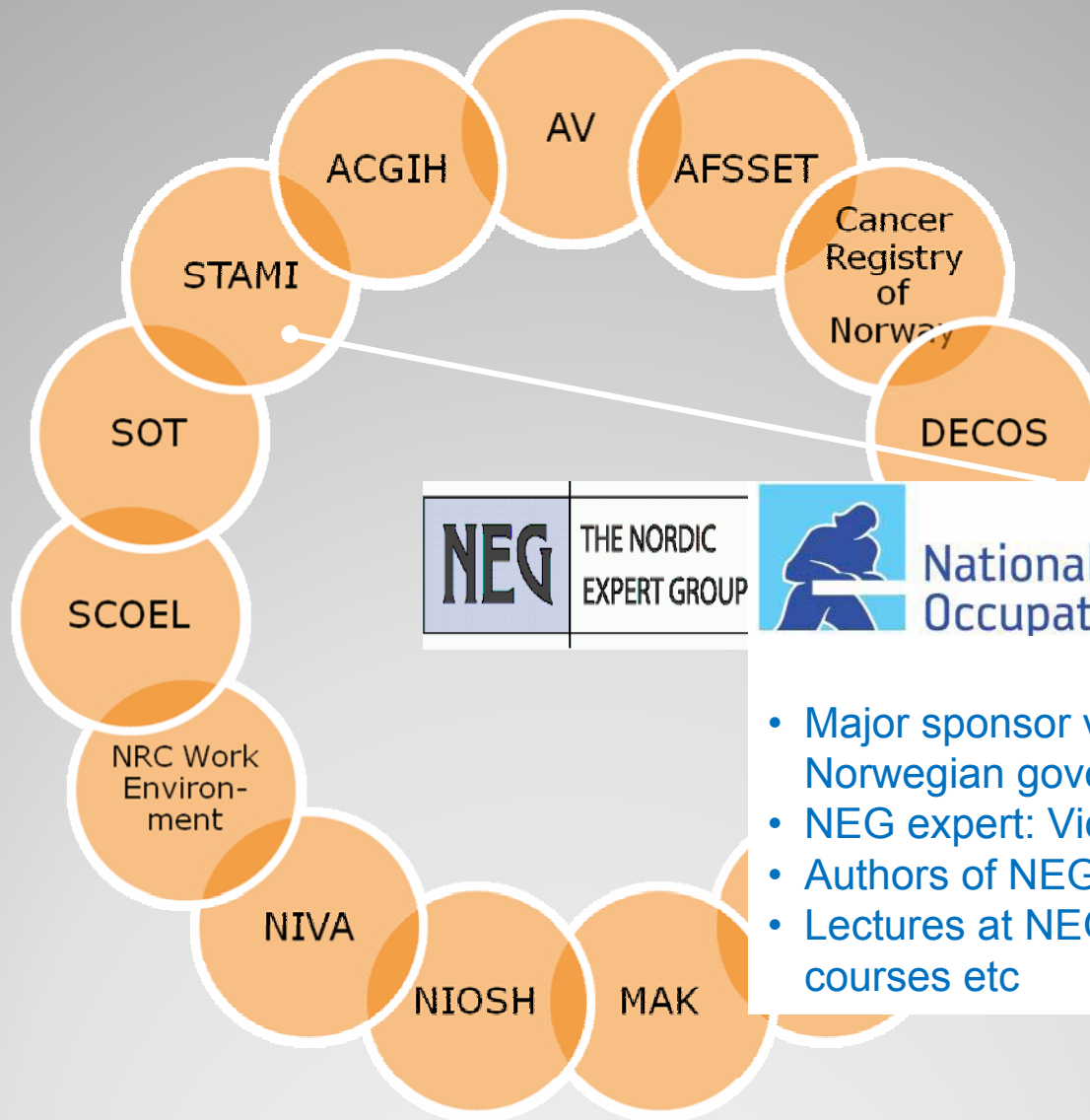



**SWEDISH
WORK
ENVIRONMENT
AUTHORITY**

- Major sponsor
- NEG secretariat
- Lectures at NEG-NIVA courses
- Joint KI-SWEA seminars



Network & collaboration



- Major sponsor via Norwegian government
- NEG expert: Vidar Skaug
- Authors of NEG documents
- Lectures at NEG-NIVA courses etc

Network & collaboration



Karolinska
Institutet



KI- Institute of
Environmental Medicine

- NEG experts:
Gunnar Johanson, Mattias Öberg
- Host of NEG secretariat
- Authors of NEG documents, etc
- Lectures at NEG-NIVA courses

Environ-
ment

ACGIH

AV

AFSSET

Cancer
Registry
of
Norway

DECOS

FIOH

IMM

KemI

MAK

NIOSH

NIVA

NEG

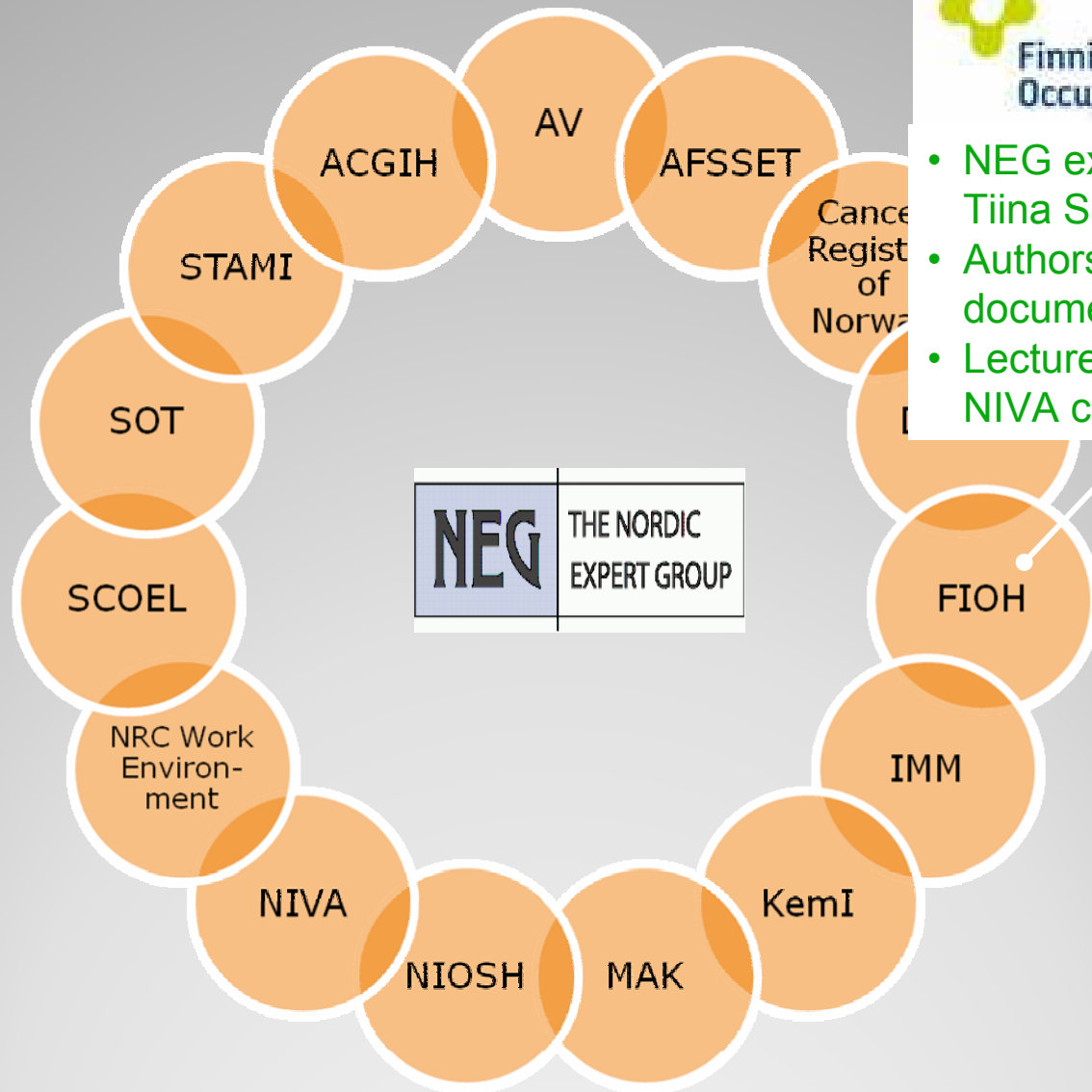
THE NORDIC
EXPERT GROUP

Network & collaboration

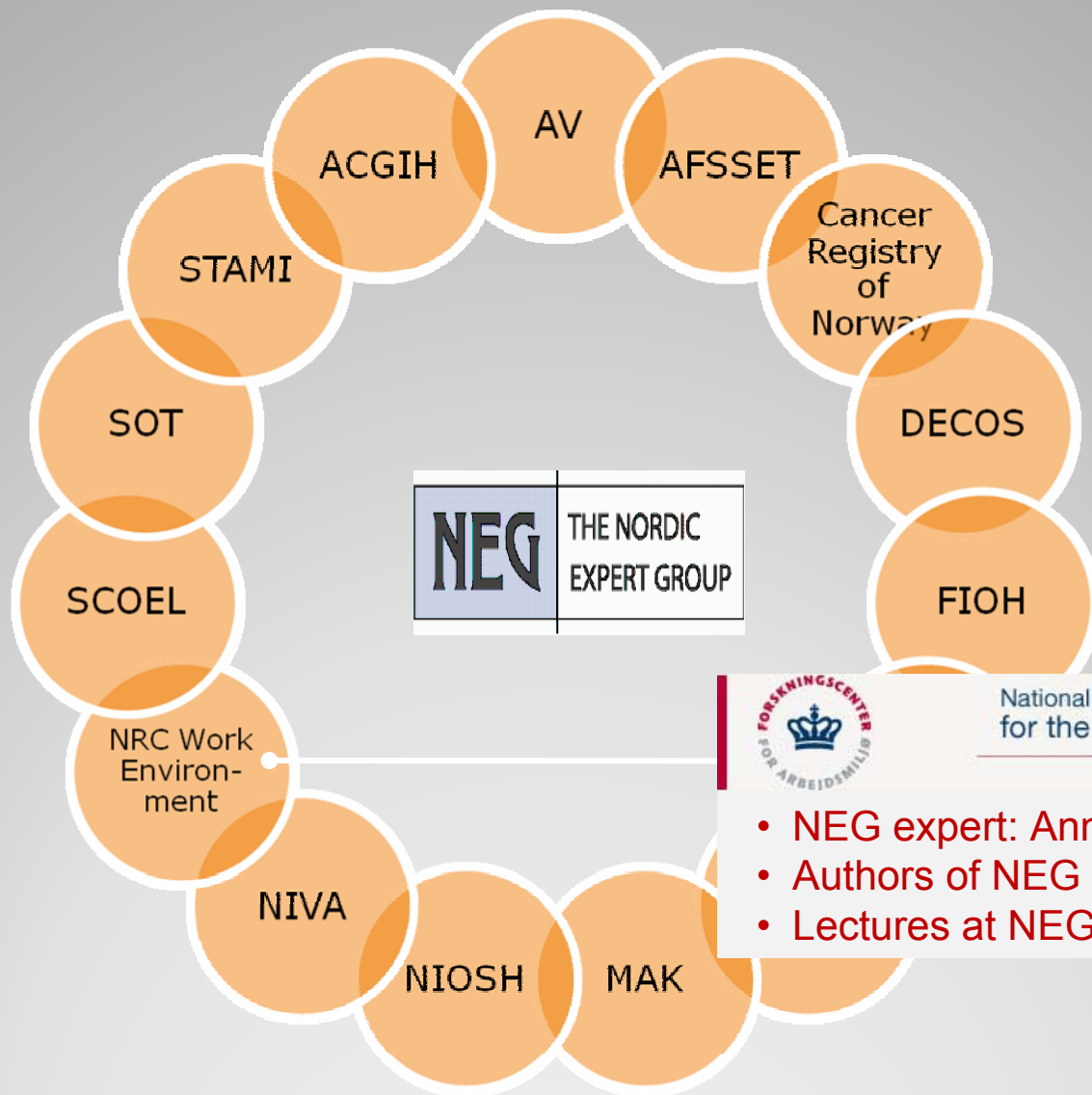


Finnish Institute of
Occupational Health

- NEG expert:
Tiina Santonen
- Authors of NEG
documents
- Lectures at NEG-
NIVA courses, etc



Network & collaboration



- NEG expert: Anne Thoustrup Saber
- Authors of NEG documents
- Lectures at NEG-NIVA courses

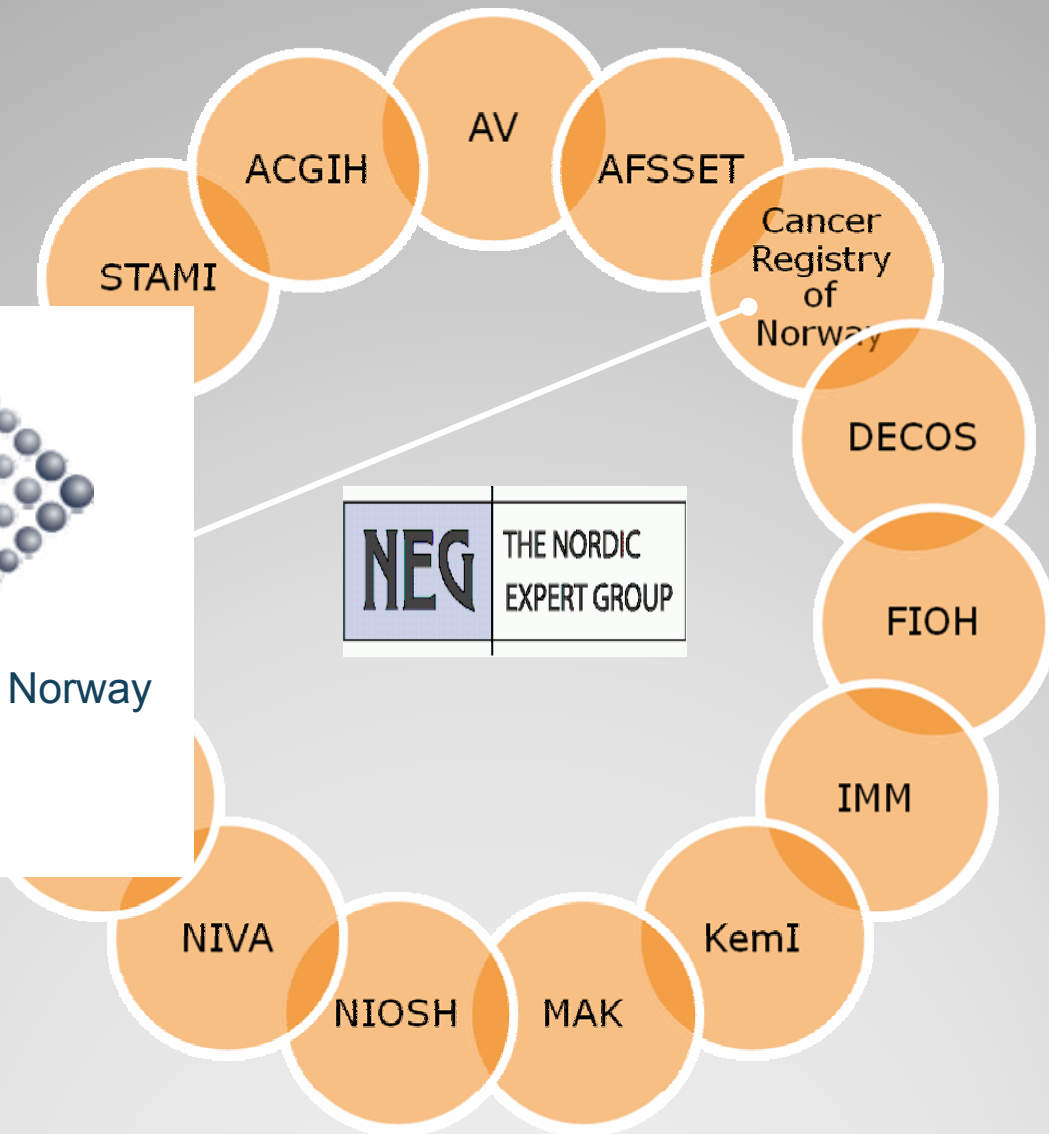
Network & collaboration



KREFT
registeret
INSTITUTT FOR POPULASJONS-
BASERT KREFTFORSKNING

Cancer Registry of Norway

Expert in NEG:
Kristina Kjærheim



Network & collaboration



Employment, Social Affairs & Equal Opportunities
Health and Safety at work

Scientific Committee for Occupational Exposure Limits

Supplies the Commission with scientific advice as basis for European indicative and binding OELs

- *NEG "represented" by Gunnar Johanson*
- *NEG documents given to all SCOEL experts*
- *NEG documents often used as basis for Sumdoc and OEL, e.g. tin, platinum, formaldehyde*
- *SCOEL members lecture at NEG-NIVA courses*

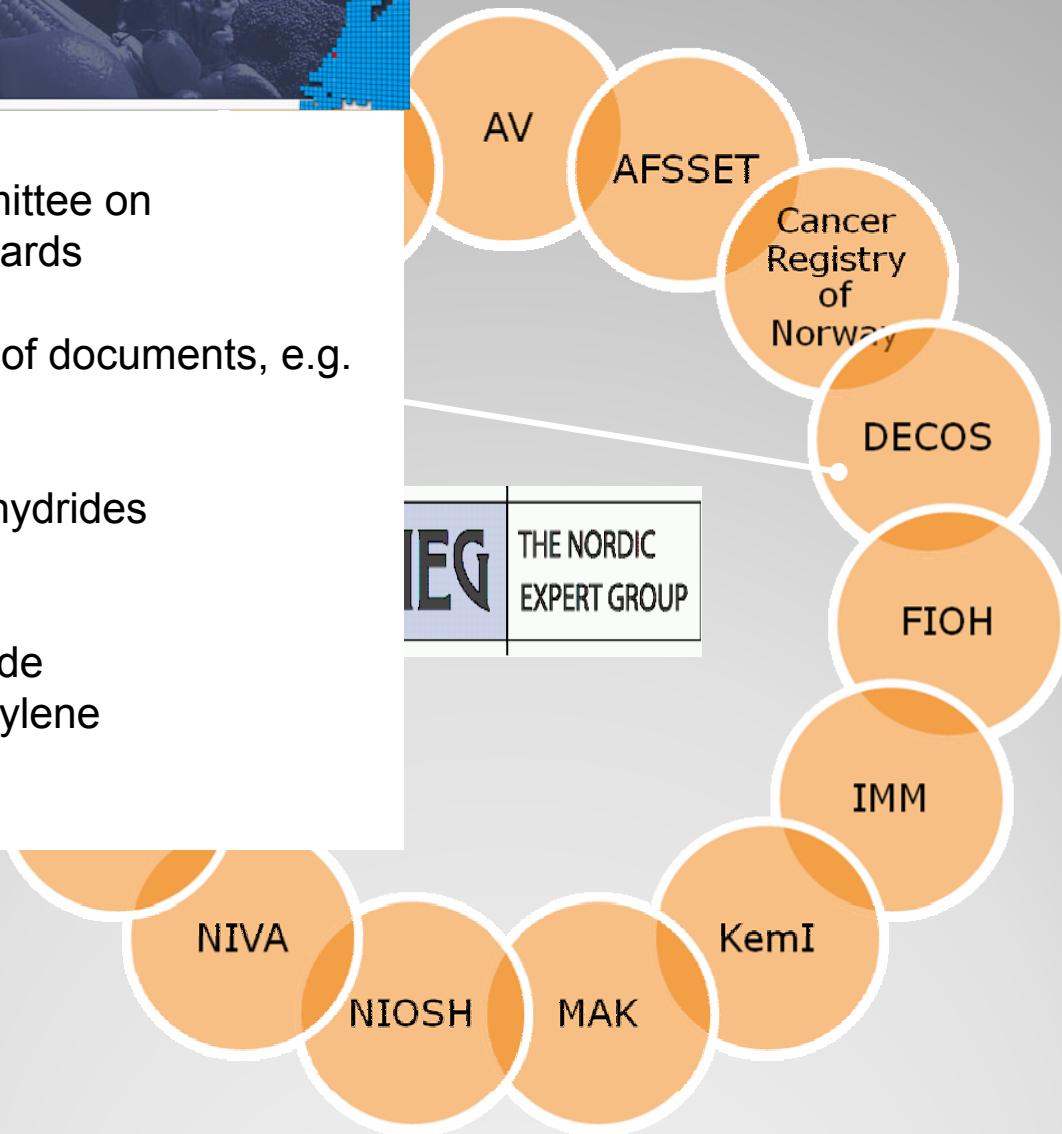
Network & c

• *NEG ⇒ increased Nordic influence in SCOEL*



Health Council
Dutch Expert Committee on
Occupational Standards

- Joint development of documents, e.g.
 - Aluminum*
 - Endotoxins*
 - Cyclic acid anhydrides
 - Formaldehyde
 - GBL
 - Hydrogen sulfide
 - Tetrachloroethylene
 - Tin
 - etc

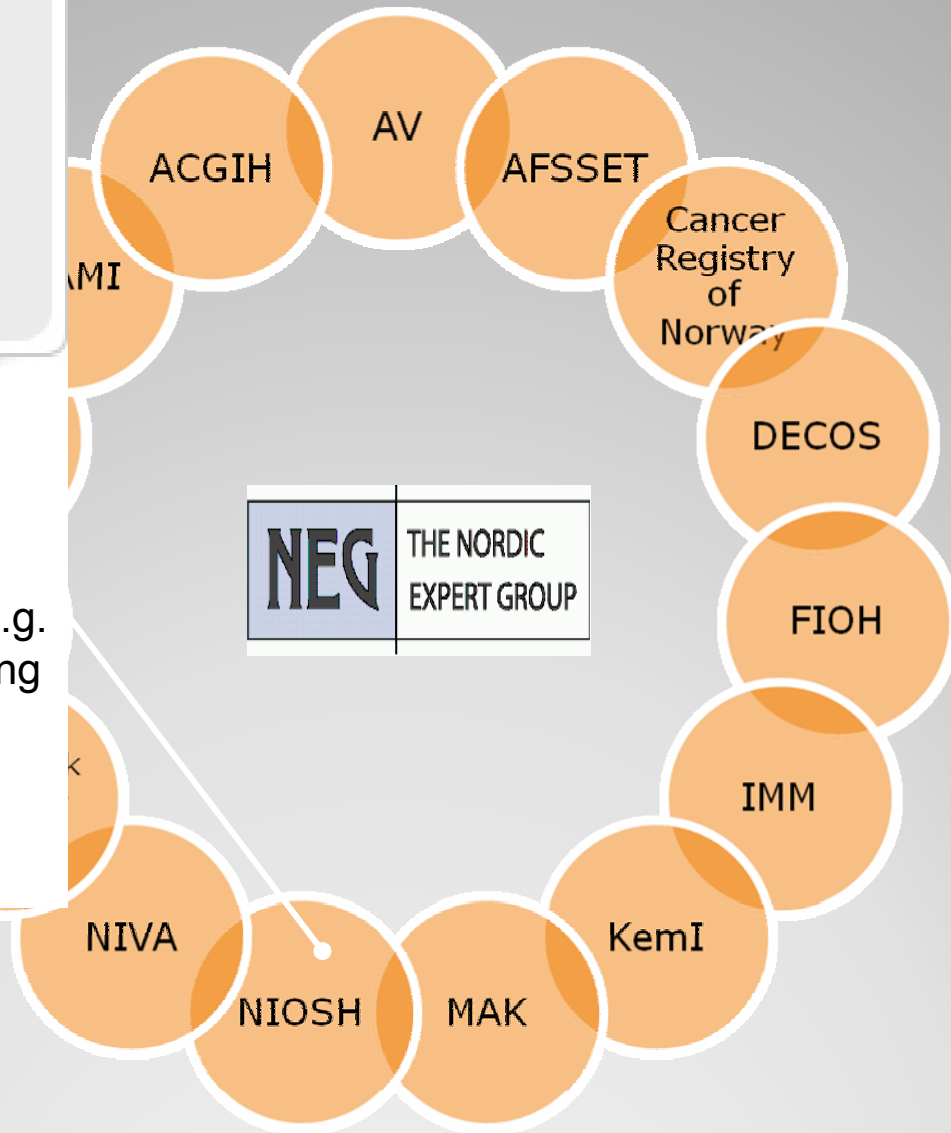


Network & collaboration



National Institute for Occupational Safety and Health

- Joint criteria documents, e.g. Organic solvents and hearing impairment
- Exchange of documents
- Lectures at NEG-NIVA courses

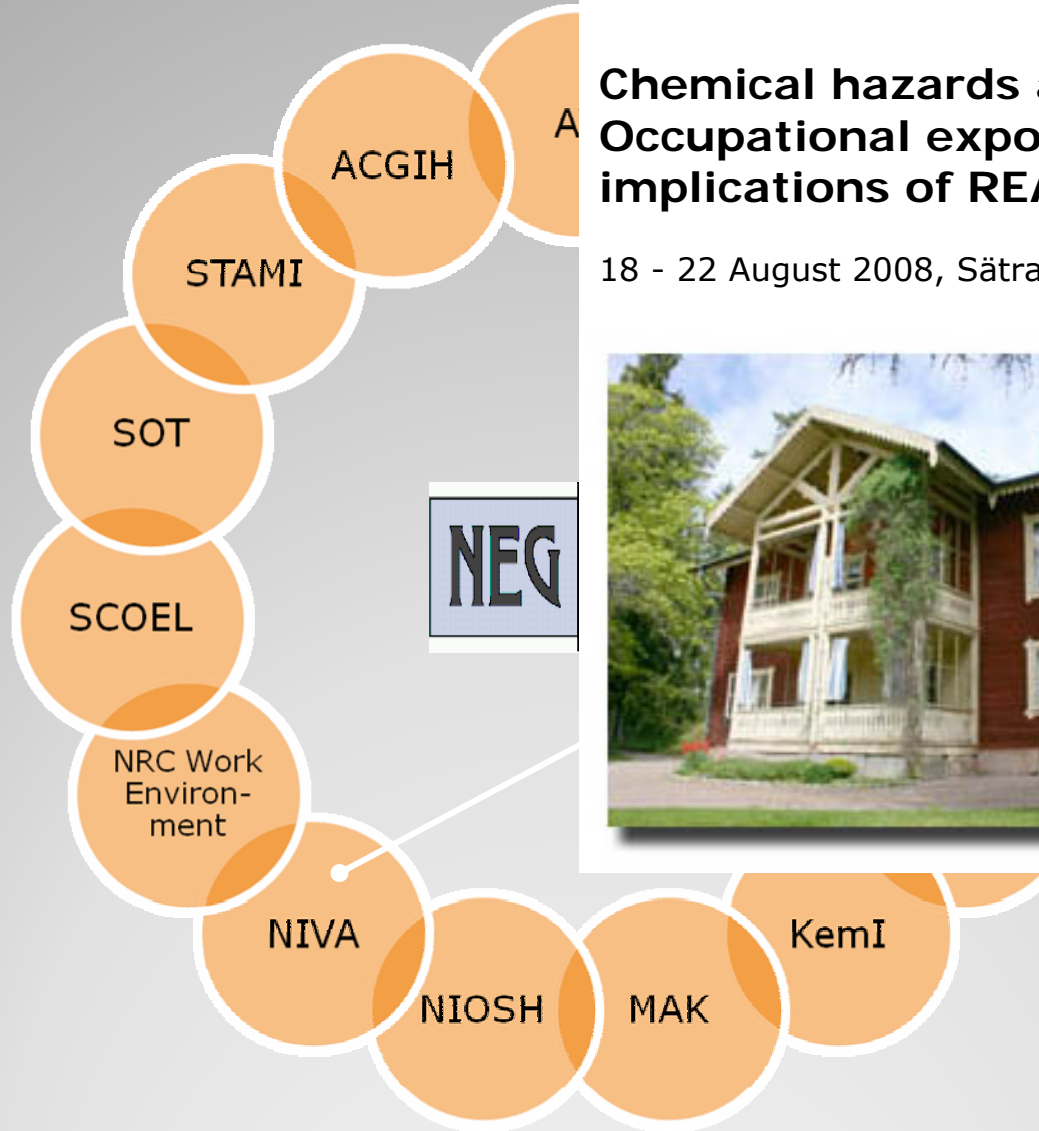


Network & collaboration

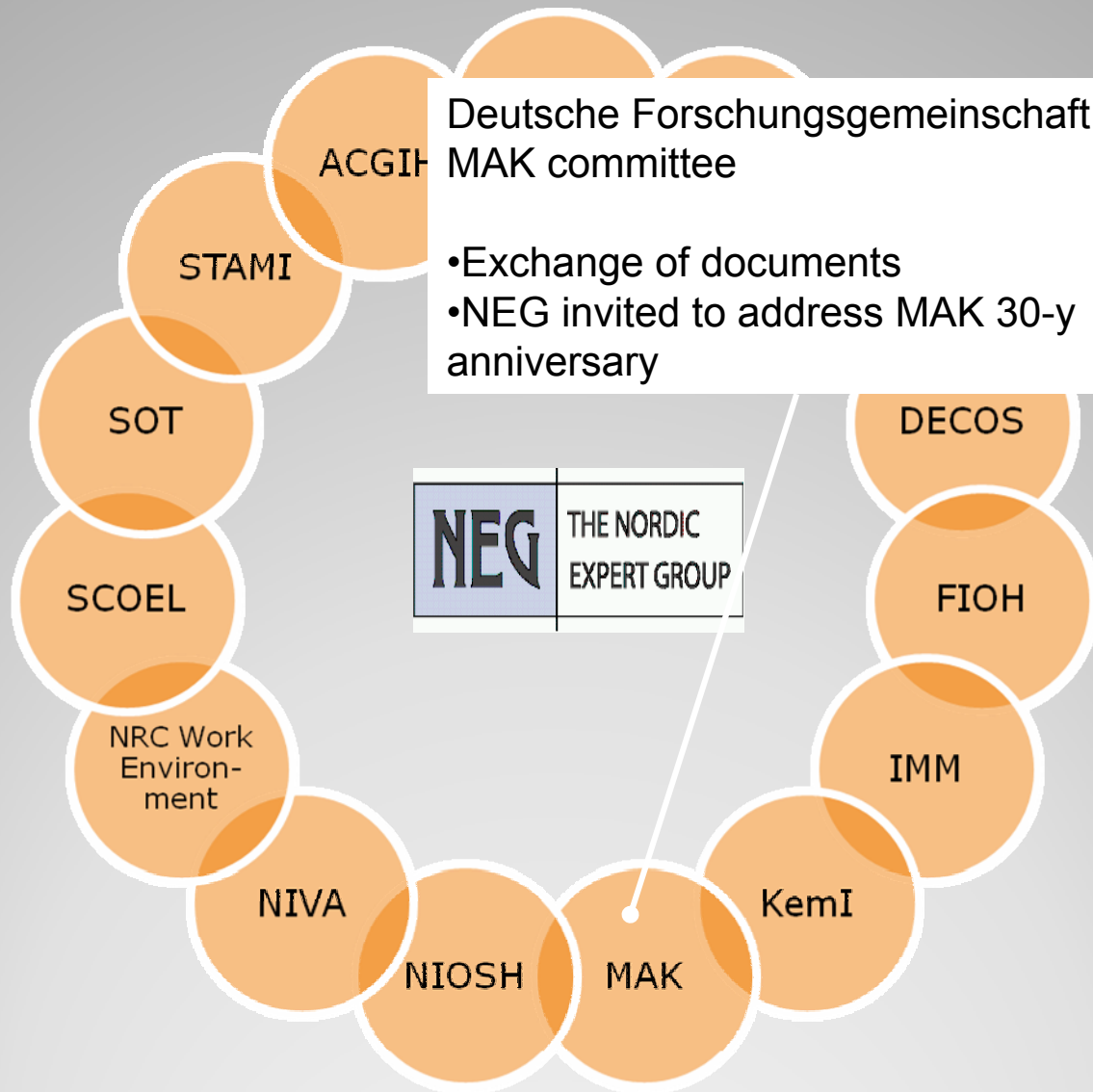
First international course on

Chemical hazards at the workplace - Occupational exposure limits and implications of REACH

18 - 22 August 2008, Sättra Brunn, Sala, Sweden



Network & collaboration

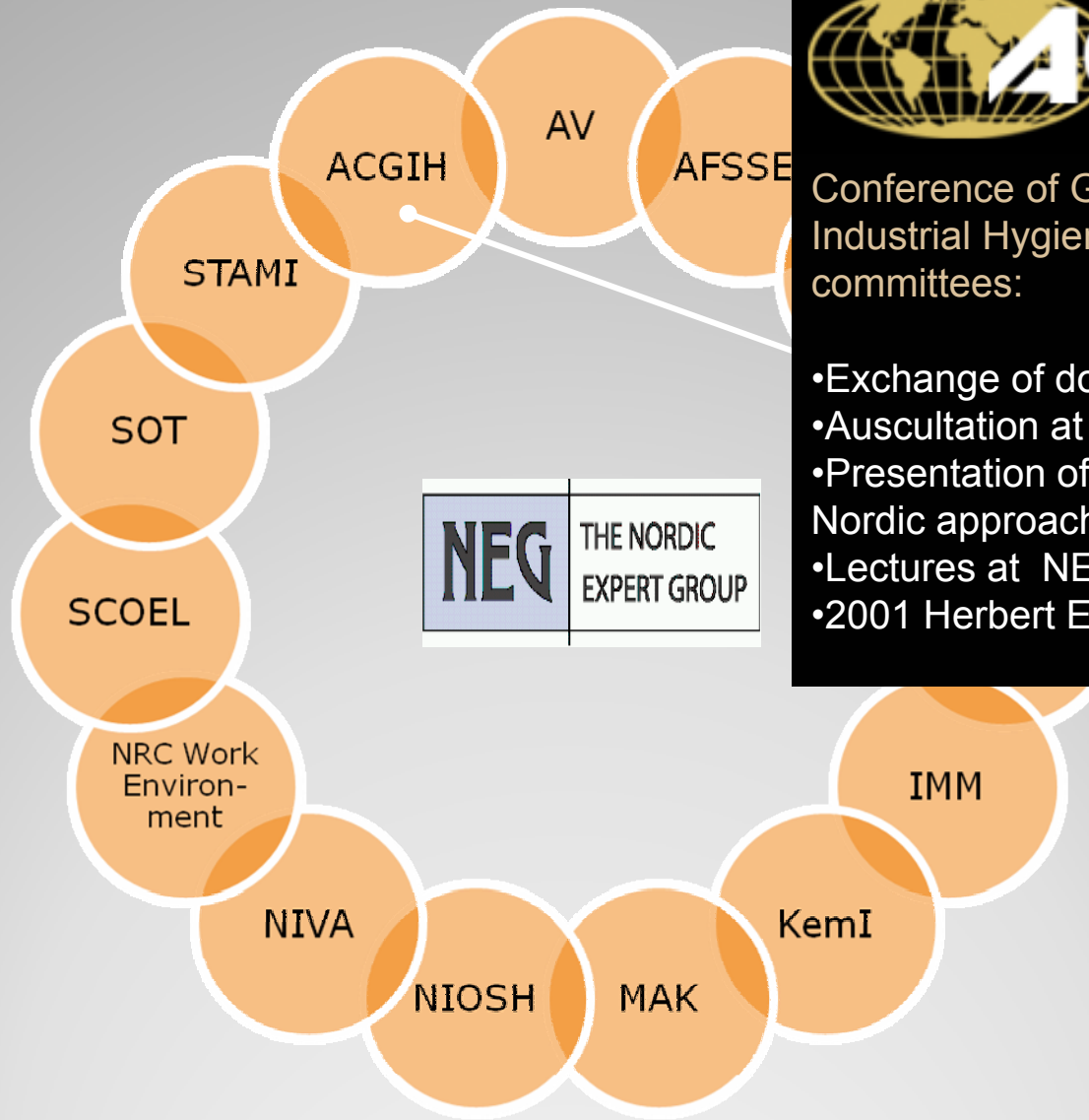


Deutsche Forschungsgemeinschaft –
MAK committee

- Exchange of documents
- NEG invited to address MAK 30-y anniversary



Network & collaboration

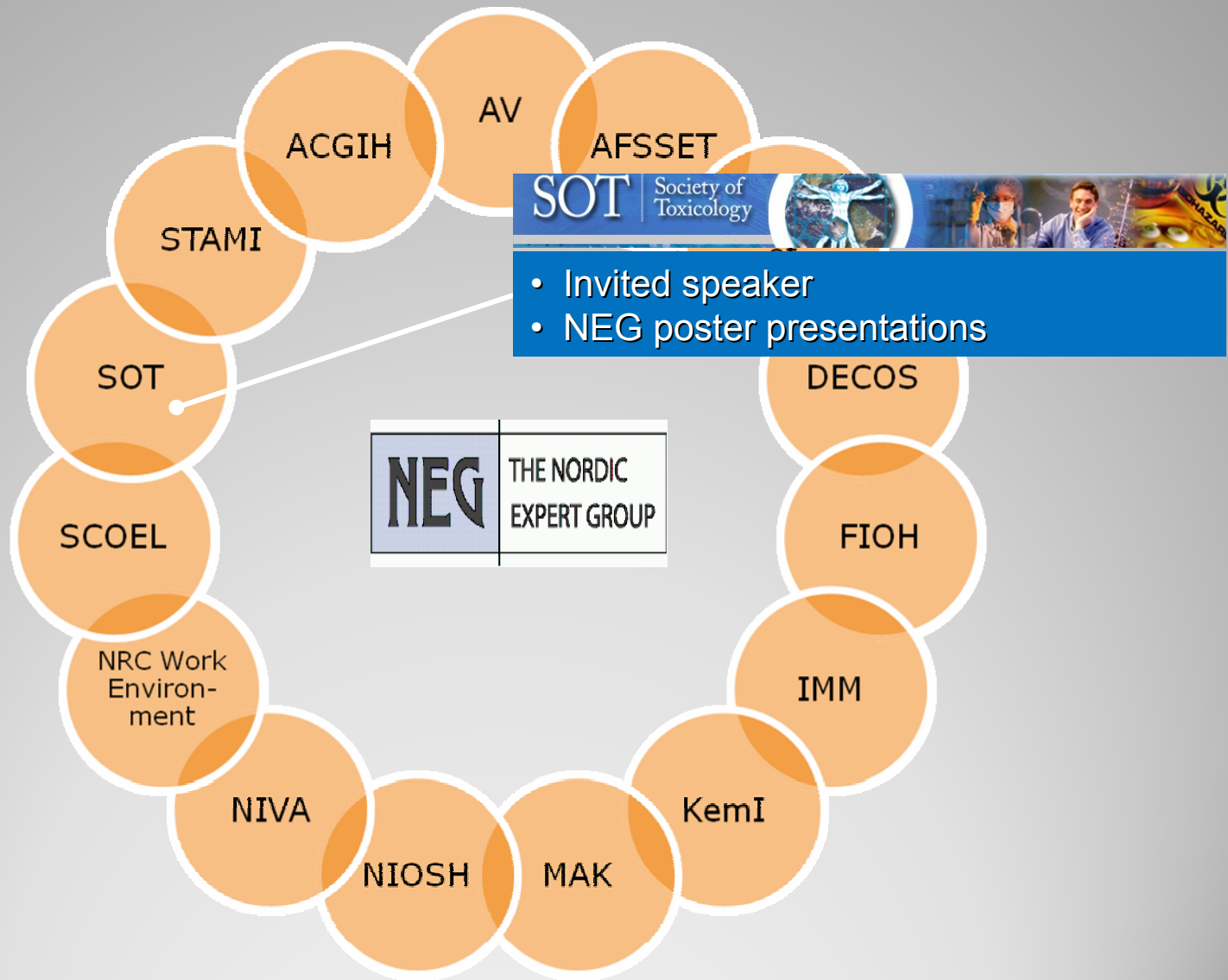


Conference of Governmental Industrial Hygienists, TLV and BEI committees:

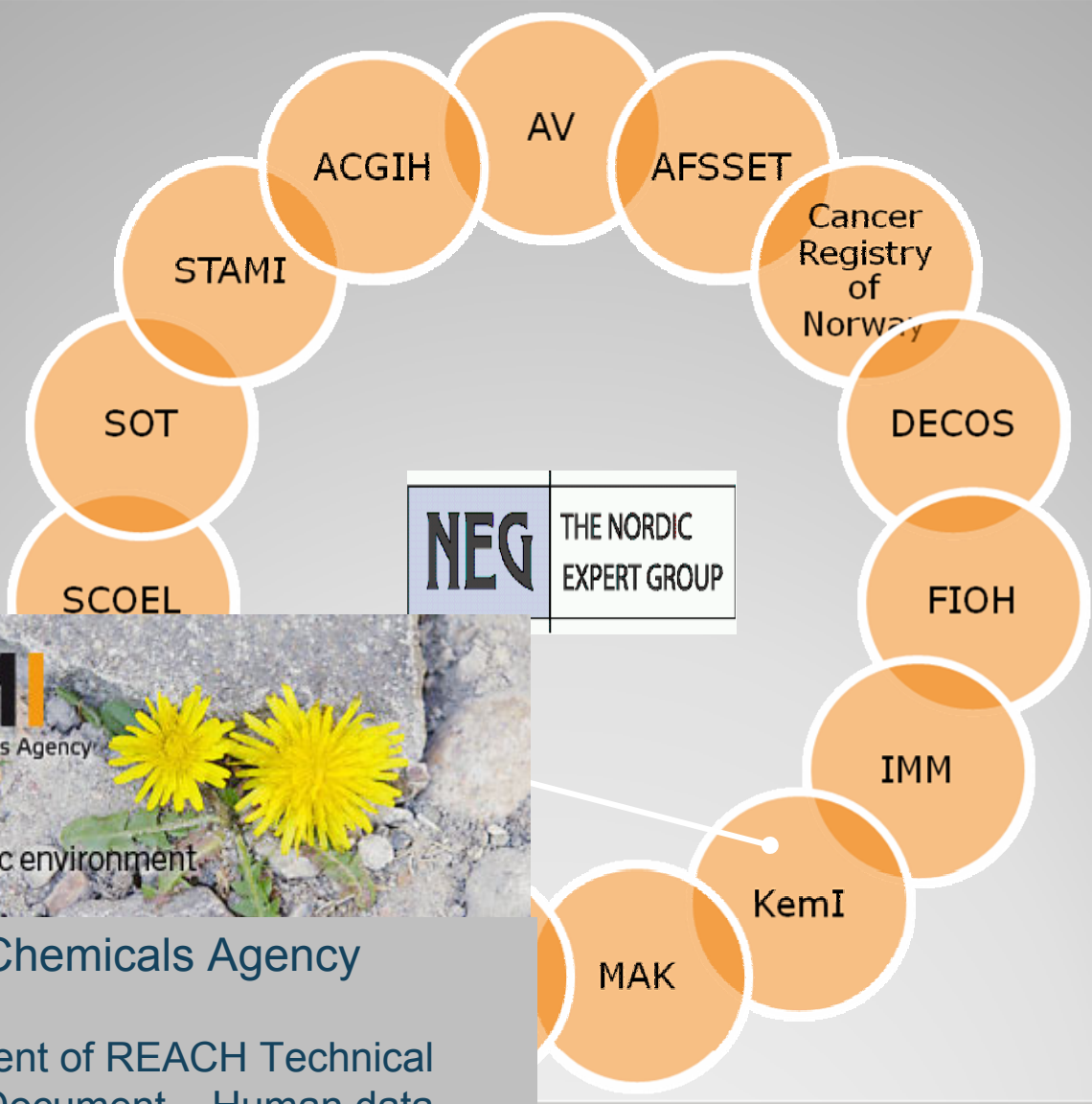
- Exchange of documents
- Auscultation at TLV meetings
- Presentation of NEG, EU and Nordic approaches
- Lectures at NEG-NIVA courses
- 2001 Herbert E. Stokinger award



Network & collaboration



Network & collaboration



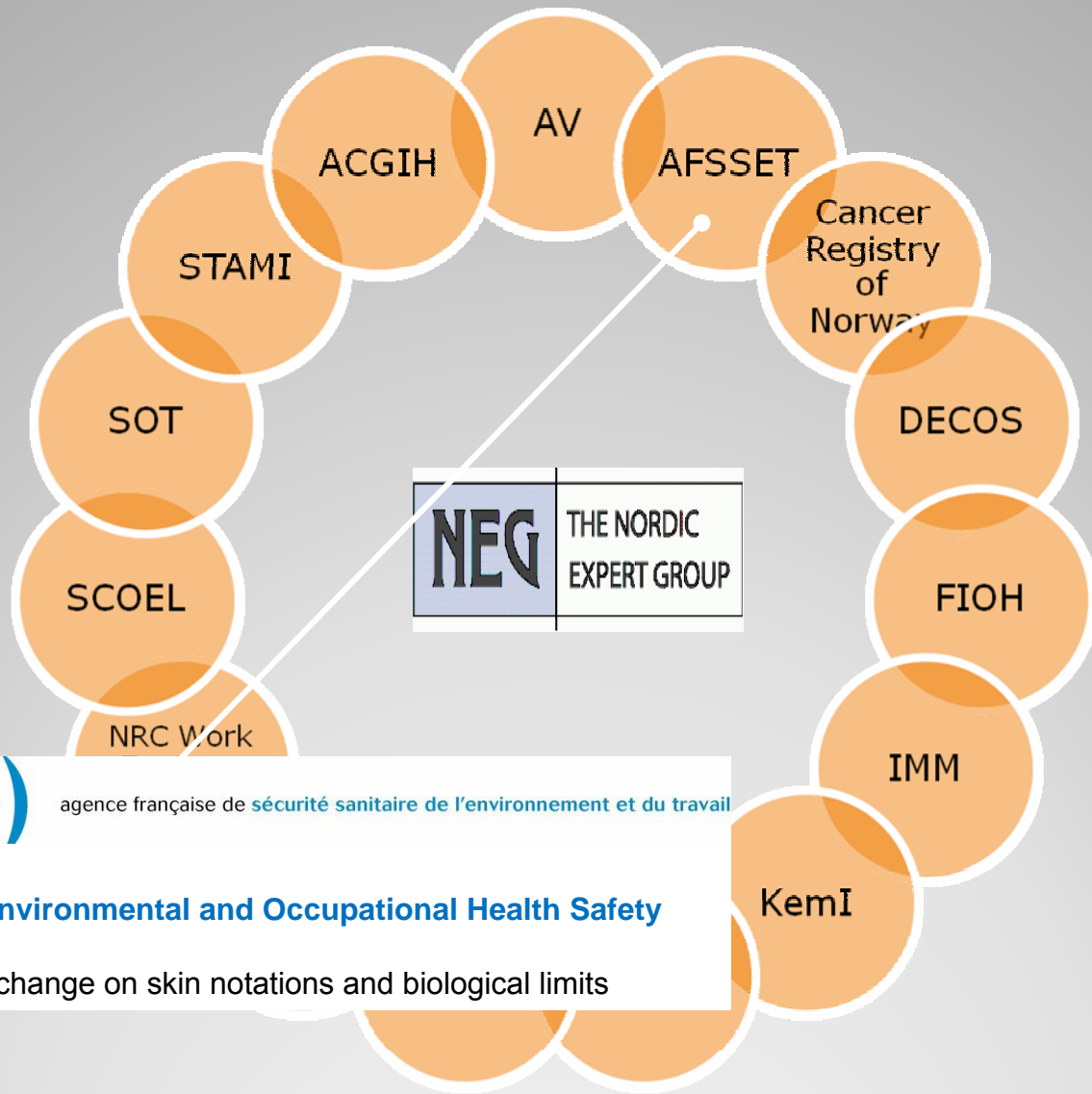
NEG THE NORDIC EXPERT GROUP



Swedish Chemicals Agency

- Development of REACH Technical Guidance Document – Human data
- Joint seminars

Network & Collaboration



afsset • agence française de **sécurité** sanitaire de l'environnement et du travail

French Agency for Environmental and Occupational Health Safety

•Presentations and exchange on skin notations and biological limits

Network & collaboration

- OELs increasingly implemented as a tool to control chemical hazards at work at European and international as well as national levels...
- ...but process is slow (only ≈ 100 OELs from SCOEL)
- International harmonisation of OELs wanted
 - compilation of scientific data
 - basis for OEL: identification of key studies, critical effect, NOAELs, use of uncertainty factors, etc
 - numerical value for OEL

OEL setting procedures

- OEL setting may be influenced by (local) risk management requirements, for example:
 - legal requirement (who is protected and how)
 - practical constraints (can it be controlled)
 - socio-economic considerations (cost versus risk)
- Scientific “fashions” may be country-specific
- Key factor must be transparency
- OELs are one of many tools to be used in control of exposure to hazardous substances (CAD, COSHH)

OEL setting procedures

Why harmonise the OEL setting?

- Harmonisation does not mean all providing an identical answer, but it does mean being able to explain differences
- Good use of scarce resources by sharing (expertise/costs)
- Can promote a higher uniform quality
- Will lead to greater confidence in OELs by Industry, Workers and Regulators
- Provided there is reasonable compliance and enforcement, it can avoid 'social dumping' and lead to sharing of best practice to reduce worker exposure

OEL setting procedures

General approach for OEL setting

- Comprehensive literature review according to current quality criteria
 - Selection of critical health end-point(s) along with knowledge of threshold/non-threshold nature and dose-response relationship
 - Selection of key studies for OEL setting
 - Understanding of the relevant exposure data for above two steps
-
- Application of appropriate and explained uncertainty factors to derive an initial 'draft' OEL
 - Identification, application and explanation of non-scientific (risk management) influences on the final development of the OEL
 - Discussion on the availability of appropriate sampling technology
 - Full documentation and publication of all steps and assumptions used in the OEL derivation

NEG stops here

OEL setting procedures

- Global production of chemicals has increased from 1 (1930) to 400 million tonnes per year
- EU chemical industry produces one third
- Chemical sector third largest production field within EU representing 31 000 companies with 1.9 million employees
- 70 000 chemicals marketed in EU
- 30 000 chemicals >1 tonne/year
- 3 800 have undergone in depth testing and are properly classified
- ≈100 OELs set by SCOEL / EU

REACH and OELs

- REACH shifts responsibility for chemical products safety from EU and member authorities to manufacturers and producers
- These are required to make chemical safety assessments (higher production volume \Rightarrow more detailed CSA)
- CSA includes development of derived no effect and minimum effect levels (DNELs and DMELs)
- DNELs and DMELs have many similarities with OELs
- Note: EU and national legislations on occupational safety and health - including OELs - remain

REACH and OELs



- HOME
- REACH
- CLASSIFICATION
- PRESS & EVENTS
- ABOUT ECHA
- WORKING WITH US

- > SOFTWARE TOOLS
- REACH-IT
- IUCLID 5

Providing help to submit registrations through technology

The allies for chemical legislation duties: REACH-IT and IUCLID 5

REACH-IT

REACH-IT provides an online company homepage to submit registration dossiers on chemicals. It also allows the Agency and Member States authorities to review the dossiers. The Agency will make non-confidential information accessible on this website.

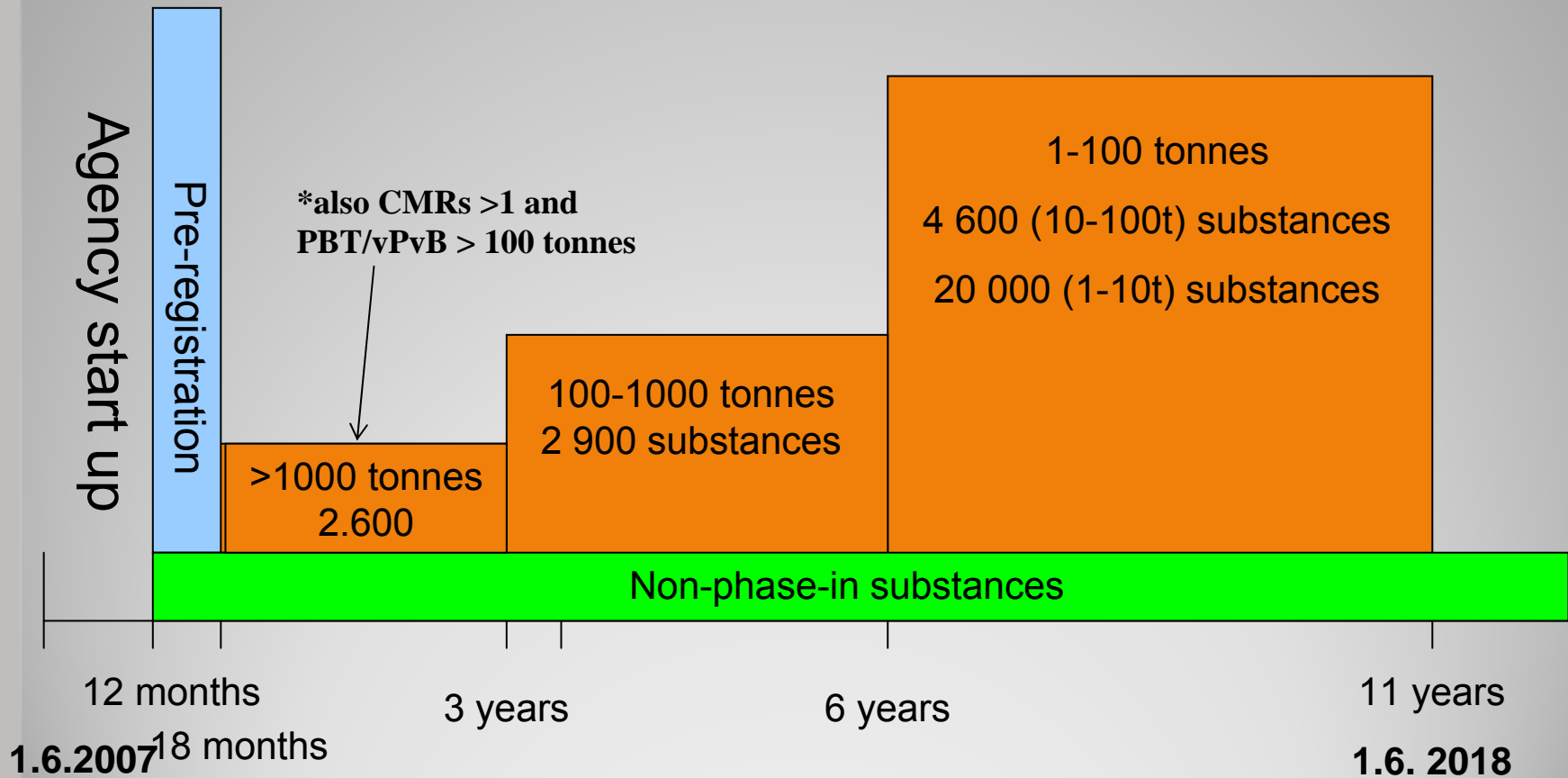
[More](#)

IUCLID 5

IUCLID 5 (International Uniform Chemical Information Database) is a software for companies to store data on chemicals and prepare for their registration to the Agency.



Registration dead-lines



REACH and OELs

Table R. 8-6 Default assessment factors

Assessment factor – accounting for differences in:		Default value systemic effects	Default value local effects
Interspecies	- correction for differences in metabolic rate per body weight	AS ^{a, b}	–
	- remaining differences	2.5	1 ^f 2.5 ^g
Intraspecies	- worker	5	5
	- general population	10 ^c	10 ^c
Exposure duration	- subacute to sub-chronic	3	3 ^h
	- sub-chronic to chronic	2	2 ^h
	- subacute to chronic	6	6 ^h
Dose-response	- issues related to reliability of the dose-response, incl. LOAEL/NAEL extrapolation and severity of effect	1 ^d	1 ^d
Quality of whole database	- issues related to completeness and consistency of the available data	1 ^d	1 ^d
	- issues related to reliability of the alternative data		

^a AS = factor for allometric scaling (see [1])

^b Caution should be taken when the starting point is a child

^c Not always covering for very young children

^d Default value of 1, unless otherwise specified

REACH Technical
Guidance Document: How
to derive no effect levels
(DNELs)

REACH and OELs

- for effects on skin, eye and GI tract via local metabolism; for effects on respiratory tract
- for effects on respiratory tract.

Human long-term DNEL for ammonia

- Human short-term studies
 - Slight sensory irritation
- Animal long-term studies
 - Increased susceptibility to mycoplasma infection
 - Histological changes in airways
- Human long-term studies

NOAEL

Assessment factors

Intraspecies	5
Exposure duration	1
Dose-response, LOAEL to NOAEL, severity	1
Quality of database	1?
Overall AF	5

Holness et al 1989: Average exposure 9.2 ppm
All <50 ppm, most <25 ppm (8-h TWA, personal sampling)
No effects on lung function, symptom prevalence (airways, eyes, skin) or sense of smell

Ballal et al 1998

≤25 ppm (gm, stationary sampling): Higher relative risk of wheezing
>25 ppm higher risks of coughing, mucus, asthma

$$\text{DNEL} = 9.2/5 = 2 \text{ ppm}$$

Swedish OEL = 25 ppm
(set 1990, now being revised)

REACH and OELs

- Long tradition and experience
- Well known and highly regarded

“...all Nordic authorities use NEG documents as major and reliable sources for OEL setting...
...large number of high-quality criteria documents...
...gratefully used worldwide...
...indispensable contribution to attaining and maintaining healthy work environment...”

*Victor Feron & Henrik Nordman
in the evaluation of NEG 1992-2001*

- Broad network
- No conflicts of interest
- Stronger voice in EU and SCOEL
- Platform to promote European and international harmonisation

Strengths of NEG

- Main task remains: Continue to produce documents on request by Nordic authorities
- Continue/enhance bilateral collaboration
- Promote European and international collaboration and harmonisation of OELs
- Move back to one-chemical-at-a-time ?
- Produce documents for SCOEL ?

- Follow up REACH Technical Guidance Document, especially regarding guidance on DNELs and DMELs ?
- Review consistency of derivation DNELs and DMELs, as performed by different producers ?
- Produce REACH chemical safety assessments, especially DNELs and DMELs, as part of chemical safety reports ??
- Review REACH chemical safety reports ???

English Danish Finnish Norwegian Swedish

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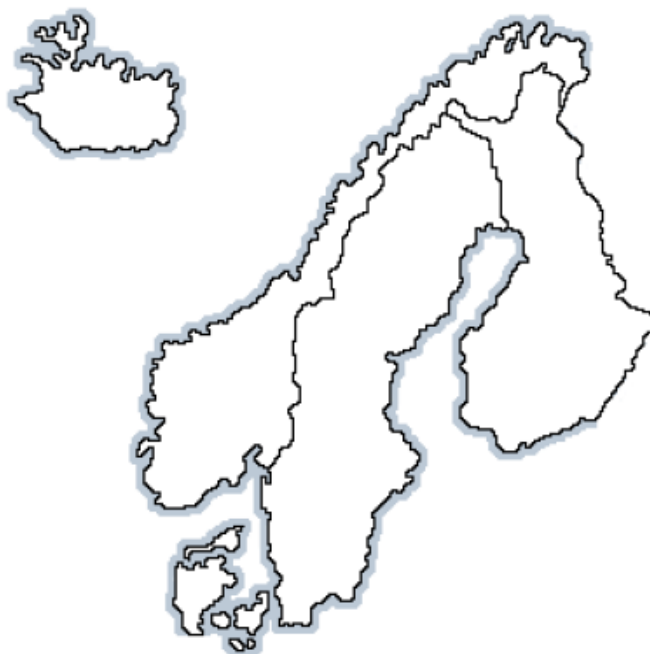
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Fungal spores

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Microbial volatile organic compounds (MVOCs)

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