Story line on the ProSafe White Paper recommendations:

A summary of the most important issues and recommendations

Numbers between brackets refer to the recommendations as listed in the white paper of the ProSafe project.

A. Regulation development. Adapt existing legislation and develop a future proof approach.

What is the problem?

Current European legislation is not designed for nanomaterials, not even for those that consist only of a single substance. Current information requirements in REACH are dependent on the production volume, and information is mostly adequate for large quantities and uniform substances. However, the quantity of each individual new nanomaterial will be much smaller than that of the bulk chemicals that we usually regulate to date. So small that, according to the current scope, REACH will not even apply to many of them, and no information about safety can be requested. In REACH information has to be provided to assess the safety of individual substances. However, new nanomaterials are becoming so complex that one nanoparticle may consist of different components, to which different regulations apply. No existing regulation may be adequate to request all of the information necessary for the risk assessment of complex nanomaterials. The development of nanomaterials will be slowed down when safety is only considered once the nanomaterial has been produced and is ready for market introduction.

What are the recommendations?

- Revise the REACH annexes. Include a legal definition of nanomaterials in REACH, and provide a more robust legal basis for additional nanospecific requirements. Information on particle size distribution, shape, porosity, and surface chemistry should be added to the information requirements. Pay special attention to aquatic toxicity testing of non-soluble manufactured nanomaterials. Develop or update guidance documents for the use of experimental data to ensure that data used for risk assessment, have a regulatory relevance. (8, 10, 11, 12)
- Create legislation that is also fit to deal with new and unknown risks (regulatory preparedness). Anticipate risks from the start of the design process. Explore and develop possible options for a “future proof approach to risk assessment” which is also applicable to next generation nanomaterials. Possible options that could be considered are concern-based testing considering risk potentials and the safe-by-design approach. (14)

B. Enabling regulation. Harmonize testing methods and strategies.

What is the problem?

It is too costly and time-consuming to test each nanomaterial separately, especially when you consider that many materials can occur in numerous forms. In addition, nanomaterials are becoming increasingly complex. This complexity and the new features provide unprecedented possibilities, but it makes it even more difficult to test safety. Moreover, test methods and strategies are not harmonized at international levels, leading to scientifically incomparable results.

What are the recommendations?

- Harmonize methods and test guidelines, in OECD and in future nanosafety projects. (1, 2)
- Harmonize the derivation of occupational exposure levels at the workplace. (7)
- Align substance identification with the already developed (ISO) schemes and the OECD Guidance on grouping. (9)
- Develop innovative test methods and testing methodologies, preferably based on human biology, thus reducing the need for animal testing. (13)

C. Data management. Improve quality, harmonization and transparency of data.

What is the problem?

Due to the large amount of unique materials, it is costly and time-consuming to get sufficient information for each form to assess its safety. Especially since we all generate and provide information in our own way, the information is rarely comparable, and not all separate pieces of the puzzle fit together. In order to make the best use of the limited information and to connect the pieces, we need to use the outcomes of research much more efficiently.

What are the recommendations?

- Initiate demand driven EU projects to generate experimental health and safety data. (3)
- Introduce and enforce an obligation to share the results of nanosafety research as a condition for funding project partners. (4)
- Develop and maintain a sustainable system to manage environmental health and safety data. (5)
- Give calls for nanosafety projects clear instructions to ensure that data and results generated are of a type and form which allows their use in topics of regulatory relevance. (6)