

January 2010

***BIAC perspective:
Existing and forthcoming approaches
for chemical safety and animal welfare***

Currently new and emerging chemical legislations at the national and regional levels can create a patchwork of sometimes conflicting rules and procedures. Differences in national regulatory requirements may increase the costs and time needed for the launch of new and innovative substances and lead to trade restrictions and distortions in international competition.

In BIAC's view, the OECD Environment, Health and Safety program plays a major role by helping to reduce barriers to trade, optimize the use of resources, and save time and money of both governments and for industry through co-operative work on the testing of chemicals, pesticides, biotechnology products, and manufactured nanomaterials. This is particularly the case for the OECD role in promoting appropriate measures to address animal welfare concerns related to chemical testing.

The leadership of OECD in assuring scientifically sound test guidelines is the foundation of Mutual Acceptance of Data (MAD). MAD is one of the most important elements of global cooperation to assure that chemicals and their products can be assessed accurately and used safely and effectively around the world without unnecessary duplication of animal studies. Recognizing the interdependencies of a global economy, the United Nations Environmental Program (UNEP) initiated a Strategic Approach to International Chemical Management (SAICM) in 2006. SAICM's core policy objectives (risk reduction, knowledge and information, governance, capacity building, and illegal traffic) include numerous areas of activity in which OECD and BIAC both have a long-standing, and substantial, record of impactful work.

In line with the SAICM objectives, BIAC strongly advocates for the development of national chemicals management capacities that adhere to risk-based principles in order to foster greater consistency and transparency in regulatory systems. Rather than taking positions on specific country or regional approaches to chemical policy BIAC strongly supports the incorporation of a set of "Principles for Chemical Management Systems" into existing and forthcoming policies. These principles promote:

- science and risk-based decision making
- tiered, targeted and risk-based approach to chemical evaluations
- leveraging existing information to reduce redundant testing and use of animals
- transparency and shared responsibility along the chain of commerce
- improved public confidence in chemical policies

BIAC firmly believes that a balanced combination of regulations and voluntary industry programs is the best way to achieve safe management of chemicals. Therefore, in addition to meeting global regulatory requirements, the international chemical industry, through the International Council of Chemical Associations (ICCA), has intensified its voluntary programs to complement existing laws by providing a high level of both technical guidance and economic expertise.

ICCA launched two voluntary initiatives as its contribution to the UN SAICM process at the first International Conference on Chemicals Management (ICCM-1) in February of 2006: The Responsible Care® Global Charter, a renewed commitment to expand the implementation of Responsible Care globally, and the Global Product Strategy (GPS). GPS highlights the chemical industry's commitment to chemical safety, applying safe and environmentally sound management practices, and sharing and making relevant information publicly available. Both initiatives aim to reduce existing differences in the safe handling of chemical substances among developing, emerging and industrialized countries and to support national, regional, and international chemicals policies.

The importance of science to decision-making on the safety of chemicals is more evident today than ever before. Implementation of REACH in the EU, initiatives to modernize the Toxic Substances Control Act (TSCA) in the US, the Japanese Revision of Chemical Substances Control Law (CSCL) and industry's obligations under SAICM are drivers for seeking information about chemical exposures and hazards. Acquiring pertinent information is crucial to risk assessment, risk management, and risk mitigation.

However, improving the knowledge base on chemicals is often linked to an increase in the number of animals used for toxicity testing. There is a growing interest in moving away from extensive in vivo testing to intelligent testing strategies or tiered approaches where existing knowledge from alternative approaches (e.g., structure activity relationships, in vitro data, relevant in vivo data from existing studies of related substances) are combined with estimates of exposure to determine what specific additional testing, if any, is appropriate to characterize potential risks with an adequate degree of scientific certainty. The OECD program provides an excellent forum for member countries and industry to join forces, share the work of chemicals evaluation, harmonize national regulatory requirements including test guidelines and thus eliminate unnecessary or duplicative testing and assessment, thereby reducing the use of animals. This leads to improved efficiencies in animal welfare, testing, and chemical assessment, as well as cost savings for both governments and industry.

BIAC fully appreciates and shares public concern for animal welfare in research and in the safety assessment of chemicals. However, BIAC also recognizes that some aspects of safety assessment still require data derived from animal studies. Nonetheless, BIAC – in partnership with major stakeholders such as OECD – is exploring realistic opportunities to Reduce, Refine and Replace (the 3Rs) the use of animals in safety assessment. BIAC's commitment is to promote and support where feasible the development and use of scientifically robust and reliable alternative approaches to safety assessment that embrace the 3Rs, while maintaining the ability to ensure human and environmental safety.

Since 1999, the chemical industry's Long-Range Research Initiative (LRI) has addressed the science needed to reduce and refine animal testing. LRI's mission is to identify and fill gaps in our understanding about the hazards posed by chemicals and to improve the methods available

for assessing the associated risks, thereby enabling industry and regulators to make informed decisions based on high quality information. Launched in 1999 and implemented under the responsibility of three regional centers (US, Japan, and Europe) more than US\$200 million have been invested in the LRI so far. The high scientific quality of the LRI results supports the mutual international acceptance of tests as established by OECD, which has been a major breakthrough in minimizing animal testing.

Recognizing the importance of animal welfare, BIAC:

- Encourages the use of alternatives approaches to animal testing when the scientific data generated by these alternatives are useful for risk assessment and acceptable to regulatory bodies.
- Links the validation and implementation of alternative methods to existing regulations, in order to agree on a common interpretation of results achieved with alternative methods.
- Encourages further research to develop new testing paradigms (e.g. such as the 2007 NAS Report on toxicity testing in the 21st century, which focuses on mammalian toxicity), with a systematic transition to these new approaches once they are sufficiently validated.
- Works to implement integrated (tiered) testing approaches that use results-based prioritization to focus testing on chemicals of greatest concern to public health, thus reducing the total amount of testing and animal research necessary to protect public health and the environment.
- Supports using available hazard *and* exposure data to prioritize substances for further evaluation, to efficiently use resources and reduce the use of lab animals.
- Supports integrating various government and industry chemical evaluation initiatives, grouping chemicals with similar characteristics, reducing duplication of testing and, therefore, the total number of laboratory animals tested.
- Supports coordinated testing programs and mutual acceptance of data that minimizes requirements for individual countries or industries to duplicate testing.
- Encourages agencies to work within the framework of the Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM), the European Center for Validation of Alternative Methods (ECVAM) and the Japanese Center for Validation of Alternative Methods (JaCVM), and internationally within OECD, to ensure the acceptability of data from alternative approaches in the context of science- and risk-based decision-making on chemical safety.
- Suggests that the removal of local test protocols which require repetition of tests on vertebrate animals already conducted as a condition for product approval is an integral part of the OECD outreach process. The MAD principle remains essential to prevent unnecessary use of laboratory animals.