Towards the International Acceptance of Alternative Methods!

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The proof of validation (i.e., the *process by which relevance and reliability of a method are determined for a specific purpose)* of any new method to be used in a regulatory context is purely scientific exercise, until being finally approved through independent (peer) review of its overall performance. The entire process necessary to gain regulatory acceptance at the international level comprises more than just scientific evaluation: an expert judgement on the practicability, availability and costs of the new method has to be provided. Even more important, a thorough evaluation of limitations and restrictions are key to enable the specification in which particular regulatory field a new method most likely could be successfully applied in the future.

In the 1990s, the question of whether or not specialised “validation authorities” such as ECVAM, ICCVAM, ZEBET, and others should get involved in the process of international harmonisation and acceptance at the OECD level was vividly and controversially discussed. Since ZEBET itself was established within a Competent Authority (former BGA and BgVV, now BfR) scientists at ZEBET have been constantly exposed to critical responses and issues raised from colleagues involved in the regulation (i.e., notification of chemicals, the authorisation of pesticides and biocides, or the safety assessment of consumer products). The constructive and continuous input from their side has contributed to appropriately ensure full consideration of their expectations and needs in validation studies, e.g., by welcoming their suggestions during the process of selection of reference chemicals (“gold standards”) to be used in those studies. Triggered by such experiences made at their own institution (BfR), scientists at ZEBET always felt strongly obliged to the concept of attempting to fully reach general consensus on new methods at the international level. To accelerate this process ZEBET has delegated a scientist to work at the OECD office in Paris. Moreover, ZEBET staff were engaged as members of the German delegation to OECD Expert Meetings and the Centre quite often has hosted OECD expert meetings itself, such as those performed in the fields of acute inhalation toxicity, skin corrosion, skin irritation and phototoxicity.

The presentation will exemplify several specific experiences made during validation of alternative methods in the past. This figure is going to be supplemented by an interesting and actual case in which the u sage domain of a new method accepted for regulating chemicals has been gradually extended to the assessment of the biological safety of medical devices (regulated by ISO Standard 1933).