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NEW VACCINE PRODUCTION TECHNOLOGIES AND THEIR IMPACT ON THE USE OF ANIMALS

PP. Pastoret[1], R. Sitrin[2]

[1]*University of Liège, Liège, Belgium*
[2]*Merck & Co, Inc., West Point, PA. USA*

Participants au workshop: O. W Merten, J. C. Vincent Falquet, M. Schwanig, M. Welin, I. Hegger, R. Neeleman, T van der Velden, A. Urital, S. Rene, M.E. Behr-Gross, M. Smith, J. McArdle, S. Prior, C. Schmidt, T Krell, M. Chevalier, H. Klein, U. Rosskopf-Streicher, C. Jaekel

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For new human products obtained by modern process technologies and amenable to characterization in vitro biochemical potency tests should be advocated and lead to a marked reduction in the use of laboratory animals since animal testing should be restricted to the development phase of the product.

For older complex antigens (e.g. D and T) that are not amenable to characterization, animal potency tests are still needed but should be reduced wherever possible. To completely eliminate animal testing for these antigens, new well characterized (e.g. recombinant derived) substitutes for these antigens would have to be developed. This would require an investment in development, manufacturing, and new clinical studies keeping in mind that for T. good domestic animal models do exist for feasibility studies.

For veterinary vaccines, fortunately, many attenuated vaccines or vaccines obtained by vectored technology are used, allowing microbiological or virological potency testing instead of animal testing. In this case, target animal testing should be restricted to development. For veterinary inactivated products (especially for food producing animals), cost and scale restrictions will probably preclude the use of sophisticated manufacturing technology and therefore animal potency testing either target or laboratory, will still be necessary but should be reduced or eliminated whenever possible.