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► Concept of familiarity in risk assessment - experience of the Americas**Deise M. F. Capalbo^{1,2}, Othon Abrahão^{2,3}, Natalia Modena^{4,5}, Carmen Vicien^{5,6}**¹Embrapa Environment, Rodovia SP 340, km 127.5, Jaguariuna/SP, Brazil, CEP 13918-110;²ILSI Brazil - Biotechnology Task Force, Rua Hungria 664, São Paulo/SP, Brazil, CEP 05425-070;³Futuragene Brasil Tecnologia Limitada, Avenida Dr. José Lembo, Itapetininga/SP, Brazil, CEP 18207-780;⁴Bayer Crop Science, Maipu 1210, 11th, Buenos Aires, C1006ACT, Argentina;⁵ILSI Argentina, Working Group on Biotechnology;⁶School of Agriculture, University of Buenos Aires, Av. San Martin 4453, Buenos Aires, Argentina**Abstract**

The International Life Science Institute (ILSI) is structured, in all countries where it operates, in Scientific Committees, among which Biotechnology. The ILSI Biotechnology Committees of Argentina and Brazil have been working together for a few years to identify issues of greatest interest for development and training in the various countries of the Americas. Due to their intrinsic importance for the problem formulation (the starting point of the risk analysis), the topics "familiarity" and "history of safe use" (HOSU) have stood out as shared topics of interest for this collaboration in the last 5 years. Particularly, the familiarity topic has been deeply discussed by the Committees to explore related concepts as stacked events, data transportability and similar constructs. Both topics have therefore been further elaborated, culminating in a harmonization workshop held in September / 2018 in São Paulo. The main topics addressed at the workshop were: (*) concepts of "familiarity" and HOSU in a risk analysis of GMOs; (*) applicability of these concepts; (*) some experiences of regulatory agencies in the Americas in the use of these concepts. Among the main conclusions and recommendations are: (1) The need to formalize definitions of HOSU and "familiarity"; for its relevance and its impacts on the Problem Formulation process and further harmonization; (2) The approaches and practice of agencies in the Americas are important for understanding the relevance and impacts of the terms and tools discussed; (3) Collaboration among regulatory agencies is essential to harmonize processes and verify the applicability of the terms and tools discussed; (4) The publication of the terms and definitions is essential, and therefore need to be presented in peer-reviewed scientific journals.

A Memory of the event will be made available at the ISBR2019, where a Parallel Session on "Familiarity" will also take place.