



Schweizerische Eidgenossenschaft
Confédération suisse
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SPAQA Regulatory Round Table November 17 2010, Basel, CH

Actual situation with non-OECD countries

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Brazil

National GLP compliance monitoring authority

- INMETRO (national institute of metrology)
www.inmetro.gov.br/monitoramento_BPL
- > Limited to pesticides and industrial chemicals

Situation

- > OECD “on-site visit” in November 2009
- > Monitoring program accepted at the GLP WG meeting in May 2010
- > Final decision to be taken by the Joint Meeting (November) and the Council
- ✓ Full adherence to OECD MAD will (very probably) be granted



GLP Program in Brazil

- 1995 Brazil introduced GLP requirements for registration of agrochemicals
IBAMA: receiving authority
INMETRO: monitoring authority
- 1996 Swiss TF informed that GLP studies conducted in CH were not accepted in Brazil
- 1996 First contact Swiss authority (FOPH) - INMETRO
- 1997-2001 Several meetings FOPH / OECD / IBAMA / INMETRO
- 2001 IBAMA proposed criteria for acceptance of foreign GLP studies



GLP Monitoring in Brazil

- 1996- 1999 Pre-inspection phase INMETRO
- 2000 Begin of laboratory inspections by INMETRO
- 2002 Some test facilities asked INMETRO to be inspected by Swiss authority (FOPH) → GLP Statement OECD county
- 2002 Begin joint inspections FOPH-INMETRO (BASF and Dow AgroScience)
- 2002- 2009 8 test facilities monitored by FOPH on a regular basis
- 2010 Brazilian monitoring program accepted by OECD → No more inspections by FOPH



India

National GLP compliance monitoring authority

- National GLP compliance monitoring authority
www.indiaglp.gov.in

Situation

- > Program not accepted in 2009 after OECD “on-site visit”
- > follow-up visit in February 2010: progress, but still some weakness to be corrected
- > October 2010 program was accepted by the OECD GLP WG
- > Final decision to be taken by the Joint Meeting (November) and the Council
- ✓ Full adherence to OECD MAD will (very probably) be granted



Argentina

National GLP compliance monitoring authority

➤ Argentine Accreditation Body (OAA)

www.oaa.org.ar

- > National GLP program started may 2009
- > Pesticides, biocides, industrial chemicals

Situation

- > Provisional adherent
- > Program should be “visited” in November 2010 by OECD team
- > 1st decision at the next OECD GLP WG



Malaysia

National GLP compliance monitoring authorities

- National pharmaceutical control bureau
- Standards Malaysia
- > National GLP program started End of 2009
- > Probably all chemicals

Situation

- > Provisional adherent
- > Malaysia should apply for “on site visit” at the next OECD GLP WG meeting (2011)



Thailand

National GLP compliance monitoring authority

- Department of medical sciences
- > national GLP program since June 2007
- > pharmaceuticals ?

Situation

- > Provisional adherent
- > should apply for “on site visit” at the next OECD GLP WG meeting (2011)



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***Ad hoc* observers**

China

- > Various GLP authorities, without coordination
- > GLP programs in place, training
- > No request for provisional adherence to OECD acts

Chinese Taipei

- > GLP program developed by Taiwan Accreditation Foundation