

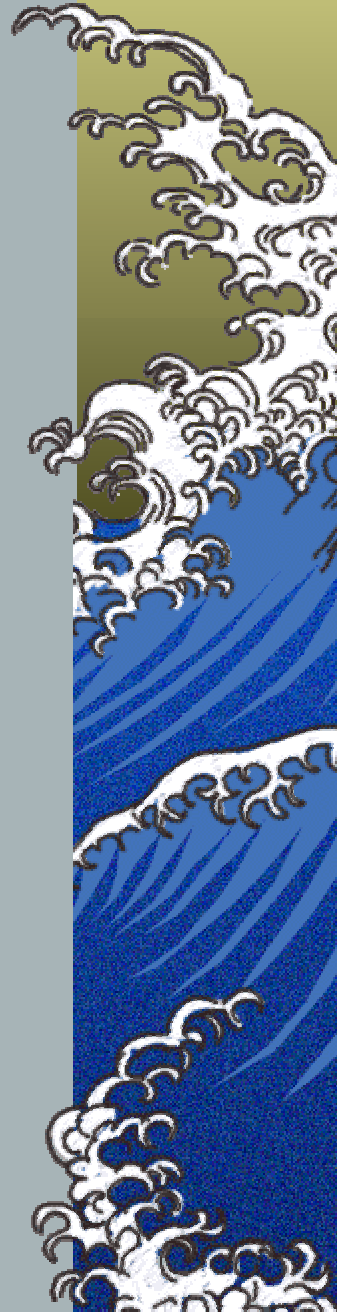
PMS 2-3 Report

ACC meeting Brunei,

December 7-8, 2005

EU Senior Expert:

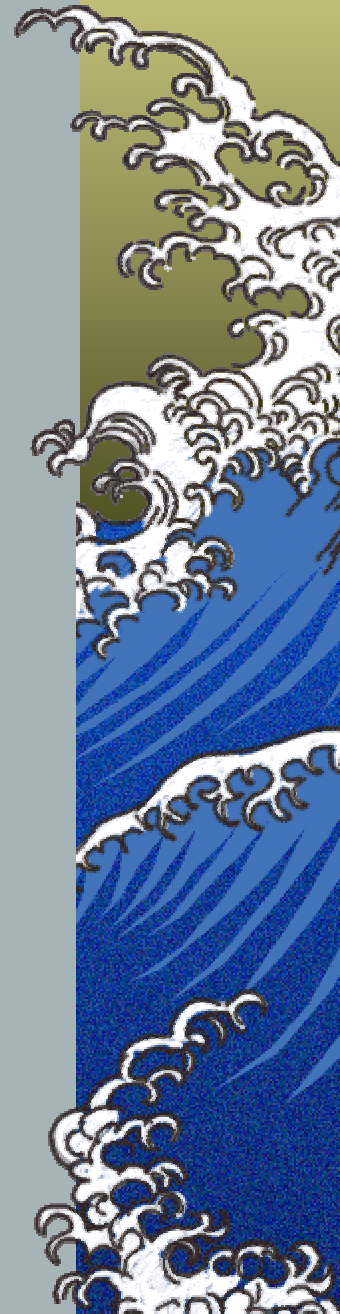
Alain Khaiat, Ph.D.



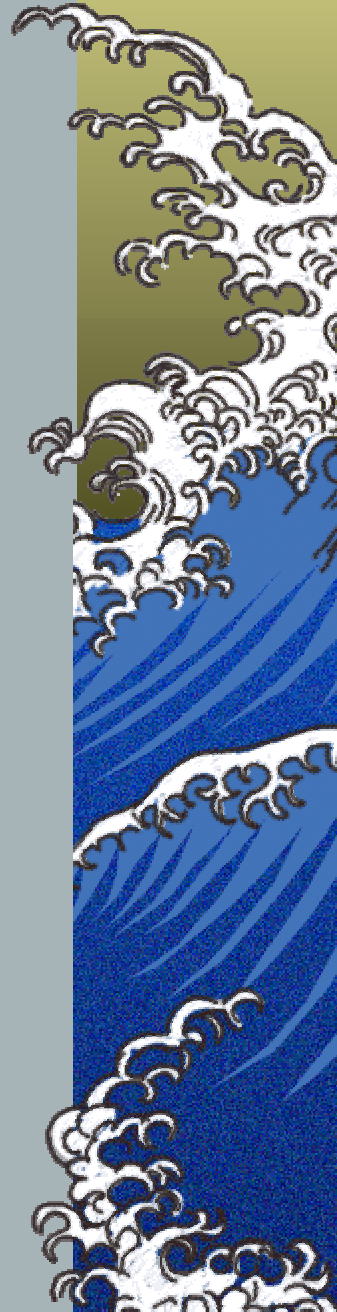
Needs to implement the Directive

(from the ACC report July 2004)

- ▶ *Training in ingredient-product safety*
- ▶ *Computerized notification system*
- ▶ *Training in auditing files i.e. product composition, safety, efficacy, etc.*
- ▶ *Consumer complaint management, including consumer information on their rights*
- ▶ *AE definition and reporting: single system across ASEAN*

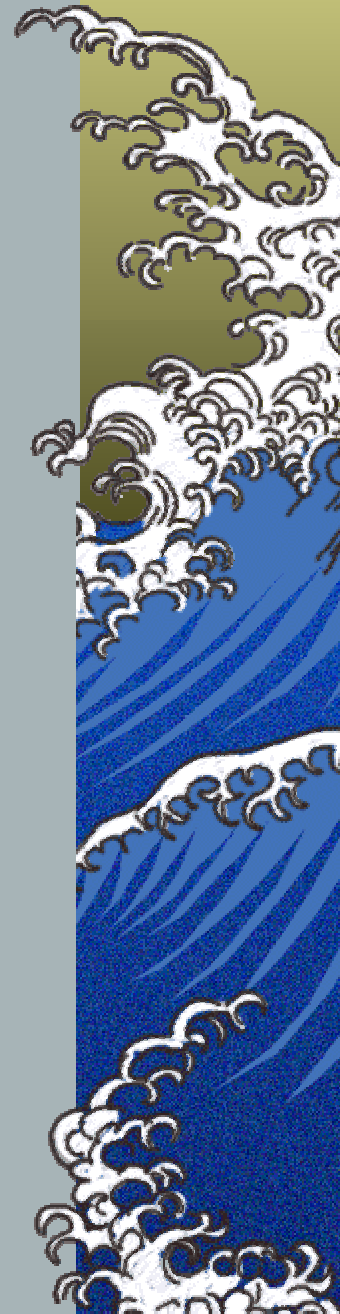


- ▶ *Liability laws: some countries do not have them*
- ▶ *Import management: some countries require certificate of product registration before importation. This will need to be changed*
- ▶ *People: will need more people in the PMS field*
- ▶ *More resources in laboratory to analyze doubtful products*
- ▶ *Strong integration of cosmetic unit with PMS units*



*But foremost:
Change in the attitude from control to
acceptance and audit*

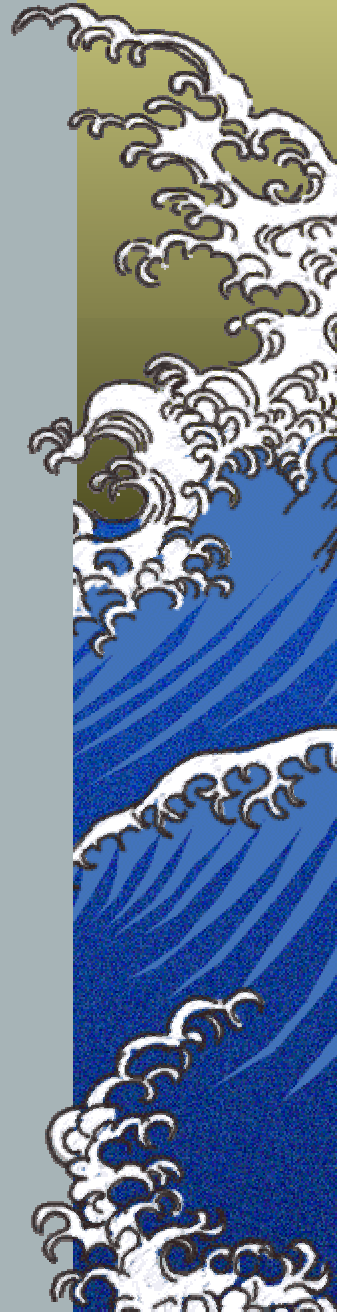
This is the most difficult part



Actions

▲ *Regional Trainings:*

- ▲ *Singapore September 27-30, 2004 for Singapore, Thailand and Laos*
- ▲ *Manila: January 24-27, 2005 for Philippines, Cambodia and Vietnam*
- ▲ *Jakarta: January 31-February 4, 2005 for Indonesia, Brunei and Malaysia*
- ▲ *Bangkok: June 7-9, 2005 on-the job training and change management training*



★ *Country Trainings:*

★ *Jakarta: April 13-14*

★ *Manila: August 3-5 (on-the job and change management)*

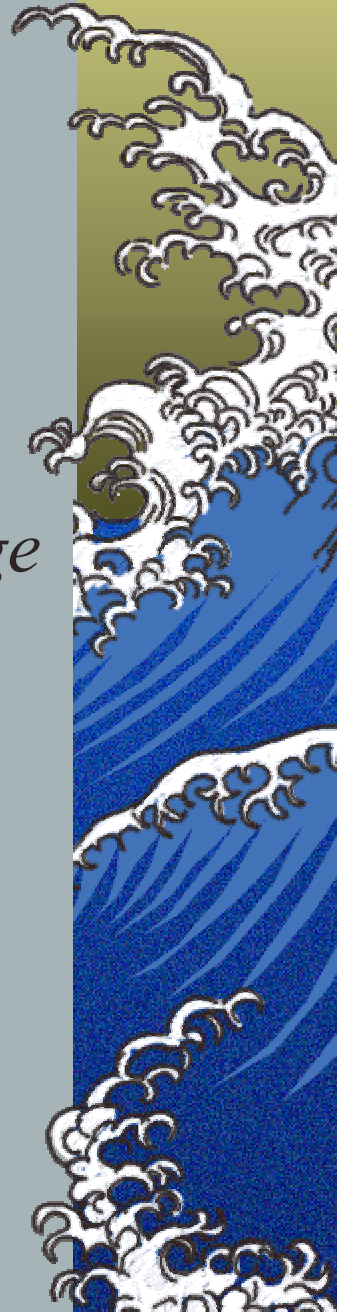
★ *Bangkok: August 17-18*

★ *Ho Chi Minh: September 7-9*

★ *Jakarta: November 29-30*

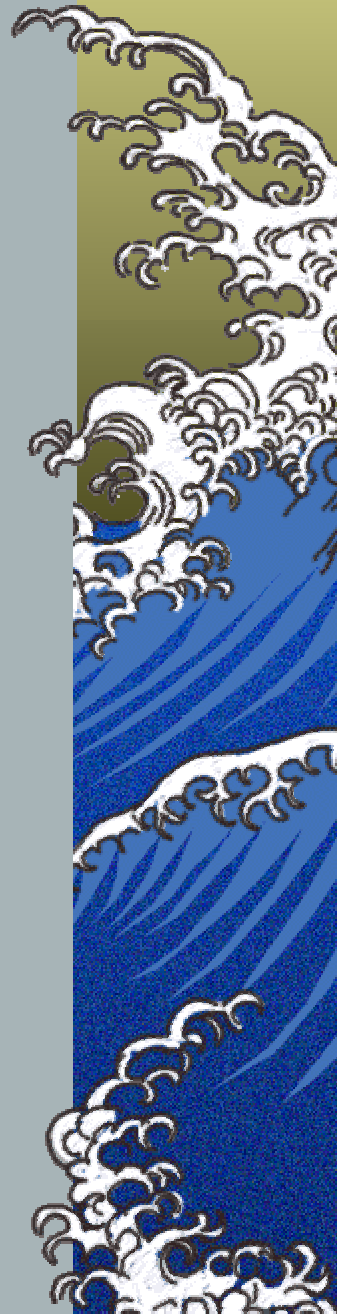
★ *Hanoi: December 13*

★ *Ho Chi Minh: December 15-16*



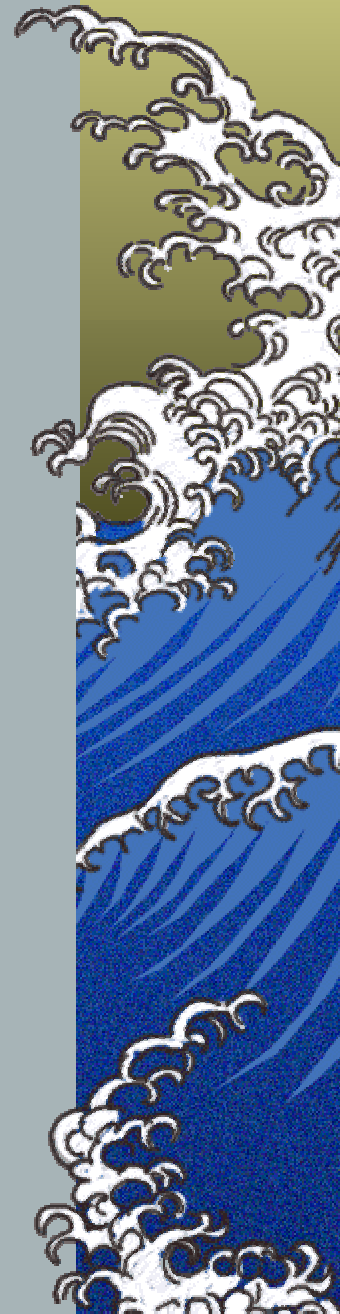
▲ *EU Training:*

- ▲ *Week of May 16th, 2005: Product safety and efficacy (PMS 2) in Lyon, France*
- ▲ *Week of October 17th, 2005: Post Market Surveillance (PMS 3) in Frankfurt, Germany and Budapest, Hungary*



Conclusion Next Steps

- ▶ *Training was adequate but too short (feedback from participants)*
- ▶ *More on-the-job training is required in each country (regulators and industry)*
- ▶ *Cascading of training have started in some countries not in others*



Recommendations

(from the ACC report July 2004)

If possible we would recommend the following:

- ▶ *Single electronic system for product notification i.e. modification of existing system where there is one, adoption of an existing system when there is none*
- ▶ *Networking of electronic systems to report major non-compliances e.g. products containing forbidden ingredients, creating risks for consumers, AE, etc. Single form, rapid exchange of information*

