APEC LSIF Update

by
Professor Dr. Pakdee Pothisiri
Vice-Chairman of the APEC-LSIF & Chairman of LSIF Expert Groups
Secretary-General, Thai FDA, Ministry of Public Health, Thailand

The ICH-Global Cooperation Group Meeting
Yokohama Royal Park Hotel, Yokohama, Japan
6 June 2006
Outcome

from
The APEC LSIF Planning Group Activity
(November 05-May 06)
The Activities

• Meeting # 1: SOM I (20 Feb. 06)

• Meeting # 2: SOM II (22 May 06)

• to ICH-GCG: the June 2006 Meeting
The Planning Group Meeting # 1

• Date :- February 20, 2006
• Place :- Ha Noi, Vietnam
• Participants :- ~ 40 from 11 economies
• Agenda :- →
The Planning Group Meeting # 1

• Agenda :-
  - Review of outcomes of LSIF III and Nov.15-16 AMM statement
  - Implementation of LSIF III recommended priority project
  - Criteria for nomination of an LSIF Champion
  - Review of LSIF TOR
  - LSIF Leadership Positions
  - ICII representative nominations (ICII GCG / ICII Q10EWG)
  - Outreach to other APEC For a
  - Contribution to the WTO
  - Plans for LSIF IV
The Planning Group Meeting # 2

- Date :- May 22, 2006
- Place :- Ho Chi Minh City, Vietnam
- Participants :- ~ 35 from 11 economies
- Agenda :- →
The Planning Group Meeting # 2

- **Agenda :-**
  - Review of Implementation of LSIF III recommended priority projects
  - Criteria for nomination of an LSIF Champion
  - Review of LSIF TOR
  - LSIF Leadership Positions
  - ICH representative nominations (ICH GCG / ICH Q10EWG)
  - Outreach to other APEC For a
  - Contribution to the WTO
  - Review of priorities for LSIF IV
  - Plans for LSIF IV
The Final Update
Final Update (1)

APEC-LSIF TOR

• New TOR
  - finalized
  - major revision – Leadership structure
  - would be sent to CTI and SOM for endorsement
  - further review in 2008
Final Update (2)

APEC-LSIF Rep. to the ICH

- Rep. to ICH-GCG
  - decided for Rep. from Jun 06 onwards
  - will decide for additional by the end of July

- summary
  → June 2006 :- Interim Rep.-Prof.Pakdee POTHSIRI
    Nominated Rep.-Dr.Ding JIANHUA
Final Update (3)

- Rep. to ICH-Q10EWG
  - Nomination Criteria:
    - developed (by Thailand) / accepted
    - will be circulated to Member
    - minor change, might be, after circulation
  - Rep. will be selected from Applications
  - **summary**
    - June 2006 :- could not Nominate
Final Update (4)

“Steering Comm. On Harmonization”

- **Establishment**
  - agreed and recommended in LSIF III
  - look on P’cals and Med.Device

- **Scope and Structure**
  - developed & agreed
  - **Summary**
    → lead by 1 Chair & 2 Co-Chairs
    → Suggestion for the Chair by end of June to PG
    → Thailand suggested Mr. Mike WARD -Chair
Final Update (5)

Implementation of LSIF III rec. priority proj.
- 4 projects + 1 additional
- need Cost Sharing – APEC + Economies
- need LSIF, and then CTI approval
Final Update (6)

The APEC-LSIF IV Meeting

- Date: September 6-7, 2006
- Place: Nha Trang, Vietnam
- Confirmation: will be informed, soon
Final Update (7)

To the ICH-GCG

- nominating Rep. :- GCG, Q10EWG
- for June Meeting :-
  - comment on Strategy on Training and Capacity-building related to the Use of ICH Guidelines
  - attend / present the Update