A meeting was held on 6 January 2004 to discuss latest developments regarding ASEAN harmonization; the implications the Directive might have on the industry and the industry's concerns where harmonization is concerned. Appended below is the minutes of the meeting.

Minutes of CTFAS Q&A Session No.1
Date: 6 January 2004
Venue: Meeting room at J&J Asia Pacific office

Participants:

1. Ms. Caroline Li (Symrise)
2. Ms. Serene Tan, Mr. Alex Chan (Prime Aromatics)
3. Mr. Chris Nottingham (Croda Aromatics)
4. Ms. Nemalikanti S. Rani (Biolyn International)
5. Ms. Ng Kok Sian (IFF Asia Pacific)
6. Mr. Oliver, Mr. Paul, Ms. Susi (Revolution Cosmetics USA)
7. Mr. Lau MT (LPS)
8. Mr. Tay Wee Siong (Takasago)

In Attendance (CTFAS Committee)

Dr Alain Khaiat (chair)
Mr. Michael Wong
Ms. Tan Kah Leng
Ms. Wah May Leng

1) Opening of session

Dr. Khaiat opened the session by saying that the emphasis of the meeting would be placed on updating those present of the latest developments regarding ASEAN harmonization, discussing the implications the Directive might have on the industry as well as finding out, through a Q&A session, the industry's concerns where harmonization is concerned.

2) Update on the developments of ASEAN harmonization (Dr. Khaiat)

The agreement for ASEAN harmonization was signed in September 2003 and the date of implementation was set at 1/1/2008.

A review of the ingredients in the ASEAN Cosmetic Handbook would be carried out in conjunction with the implementation of the Directive. Members who are using any of the ingredients in the Handbook should inform CTFAS in order for CTFAS to work towards making their point of view known during the review.

The EU has passed a decision that makes it compulsory for cosmetic manufacturers to declare the presence of 26 fragrance

ingredients if they are present in the product above the stated concentration. There may be pressure in the future for ASEAN to incorporate this decision into the ASEAN Directive.

Local manufacturers would be required to comply with the cosmetic GMP guidelines and may be required to show proof of compliance, in the form of a GMP certificate. In Singapore, the certificates are to be issued by the HSA following an audit.

Notification would be required at least one day prior to the importation of a cosmetic product once the Directive is in place. The notification form has been proposed but not finalized and will be made official to all local authorities once finalized. HSA has announced that they will move directly into the Directive without implementing MRA.

Existing regulations in the importing countries will apply before the Directive is implemented.

Once the Directive is in place, the person or company placing the cosmetic product in the market will be fully responsible for assuring the safety, under foreseeable conditions of use, of the product. Information that can serve as testimonials of the product's safety are also to be kept at hand for review by authorities.

The future role of the regulators would be to ensure the industry's compliance to the Directive via market and dossier checks.

The clause in the EU Directive referring to animal testing does not appear in the ASEAN Directive.

3) Q& A session

Q1: What would the new EU Decision for labeling of fragrances apply to? (Revolution)

A: To any cosmetic finished product containing any of the 26 fragrances. It does not apply to raw materials.

Q2: Can we have more information as to where we stand where animal testing is concerned? (Croda)

A: In the EU, the use of animals has been banned for tests where alternative methods are available whereas animal testing is still, at the moment, permitted for tests without alternative methods.
The clause on animal testing is not applicable to the ASEAN Directive and there is also no pressure at the present moment to make it applicable.
This is good as there would be no pressure on the ASEAN industry to develop alternative methods but bad as the difference would eventually become a barrier in trade between

ASEAN and EU.

Q3: Is cGMP absolutely necessary? How can local manufacturers learn more about cGMP? Would it be possible for local manufacturers to obtain any form of funding? (Revolution)

A:
- Compliance to cGMP is pivotal in the compliance to the ASEAN Directive. Presently, the certificate of GMP is required for import into Malaysia.

- Local manufacturers can learn more about cGMP through GMP courses. At the present moment, Singapore Polytechnic and some private consulting firms offer such courses. HSA may also be conducting courses in the future. CTFAS will compile a list of the available courses for circulation within the association.

- We are not sure if funding would be available. CTFAS will try to find that out.

Q4: Will CTFAS be able to issue GMP certificates? What would the price of an audit be? (Revolution)

A: No, the certificates will be issued by HSA. The price of a GMP audit is not known yet.

Q5: Has the cGMP been defined? (Croda)

A: Yes, it has been defined by the cGMP guidelines.

Q6: Will Malaysian authorities accept GMP certificates issued by the HSA?

A: Yes, they are bound by the Directive to do so.

Q7: The lack of knowledge on cGMP and auditing procedures is worrying. (Revolution)

A: Agreed. CTFAS will try to work towards helping local manufacturers find means of gaining that knowledge. CTFAS will also liaise with the HSA to make the audit and issuance of certificates faster.

Q8: The local industry might have difficulties in terms of cost. (Croda)

A: GMP is, on the long run, cost saving and should not be a cost burden. Manufacturers should try to look at GMP as a form of investment.

Q9: Are there specific formats for the safety evaluation reports that are to be kept at hand for review by the authorities? (Symrise)

A: No, there is no specific format. The only requirement by the Directive is that the product is safe.

Q10: How will the safety requirements be enforced? (LPS)

A: The industry is bound by the Directive to keep proof of product safety on their premises and to conduct post marketing surveillance on their products.
The authority will then ensure compliance by reviewing these documents, conducting in market checks and investigating consumer complaints.

Q11: So will all products have to be registered after implementation? (Revolution)

A: No. Before implementation, the current regulations are applicable, so only category I products need to be registered. After implementation, no products will have to be registered but all products will have to be notified. This means that safety assurance by the importer and self-regulation by manufacturers will become very important. It is suggested that importers conduct regular audits of their suppliers.

Q12: Is there a published list of the data required to ensure product safety? (Croda)

A: No. For the importer, there is no actual need to understand how safety evaluation is conducted. The more important thing would be for the importer to audit the supplier (the manufacturer) to ensure that safety evaluation is being conducted by a qualified person. Local manufacturers must ensure that the person signing for the safety of the product is qualified or engage a qualified consultant to sign for the safety if such a person is not present.

There is a definite need to work with HSA to define the requirements as well as to train up the local industry where post marketing surveillance is concerned. CTFAS will work towards making this possible.

Q13: Are there specific definitions of “qualified person”? (LPS)

A: No. The only requirement is that the manufacturer can show justification of qualification.

Q14: What is the CTFAS’ stance on the labeling of the 26 fragrance ingredients? (Symrise)

A: At the moment, the clause is only present in the EU Directive and is not applicable to ASEAN. There could be pressure from consumers or member states to adopt the clause for the ASEAN Directive in the future. CTFAS will then be responsible for

defining the industry position and work towards preventing the adoption.

Q15: Is there anything within the Directive that might restrict the development of new ingredients? (Croda)

A: No. New colorants, sunscreen actives and preservatives will be subject to evaluation but other ingredients can be used freely as long as its manufacturer can assure its safety. CTFAS is more concerned about those ingredients listed in the ASEAN Handbook that are up for evaluation that we would have to work towards retaining if they are currently being used by the local industry.

Q16: When will the evaluation of ingredients in the ASEAN Handbook be conducted? (Croda)

A: By 2011.