The Minutes of the Proceedings of the 2nd Meeting (in the fiscal year from 2009 to 2010) of "The Advisory Council about the Studies on the Development and the Evaluation of Ultramodern Safety Test Methods Considering International Trends

Date: November 11th, 2009 (Thursday); 14:00 to 17:00
Place: The Lecture Room, National Institute of Health Sciences (NIHS)
Attendants: Tsunehiko Iwai (Shiseido: Japan Cosmetic Industry Association), Hiroshi Ono (Food and Drug Safety Center Hatano Research Institute Japan), Yasuyuki Sakai (the University of Tokyo), Fumio Sagami (Eisai, Japan Pharmaceutical Manufacturers Association: JPMA) Fumiaki Shono (Japan Chemical Industry Association), Takatoshi Kuhara (Juntendo University), Keiko Yamazaki (The Organization for Communication of the Societies to Think of Living-together with Animals)
Observers: Yasuo Ohno (NIHS: the chairperson), Masaki Shibatsiji (the Ministry of Health, Labour and Welfare: MHLW), Kunihiko Yamaguchi (the Ministry of the Environment), Fuyumi Takahashi (The Chemical Daily), Hiroshi Itagaki (Shiseido), Mitsuteru Masuda (NIHS), Hajime Kojima (NIHS), William Stokes (NICEATM/ICCVAM)

Discussion topics
Before the discussion, Dr. Kojima explained the reason of holding this meeting. Because of the visit of Dr. William Stokes (NICEATM/ICCVAM) to Japan, it is nice opportunity to exchange opinions between this representative of US and the members of the Advisory Committee. Dr. Ohno then chaired the meeting, and all the attendants introduced themselves.

1. Confirmation of the minutes of the previous proceedings
Dr. Ohno required the opinions about the minutes of the previous proceedings, but there was nothing special.

2. The lecture of Dr. William Stokes

Using the reference 13, Dr. William Stokes explained the structures of NICEATM and ICCVAM, their recent movements and future plans, the activities of international organizations and the movements of the evaluation of toxicity in US and so on.
In the section of questions and answers, there were the questions including those on the future principle of the alternative methods based on the mechanisms of effects, the differences between NTP and EPA, the situation of US in dealing with the EU regulations, the complicated system of ICCVAM, the differences of the extents of weights among 3Rs, the situation of the budget in US, the situation of acceptance by the regulatory side of the test methods (the utility of the cell toxicity test for acute toxicity tests; the pyrogen test), how to think about the Tox21 high throughput assay, and the documents of OECD guidelines and guidance. Dr. Stokes sincerely responded to these questions.

3. The activity of JaCVAM and its plans for future
Dr. Kojima explained the activity of JaCVAM and its future plan using the reference 7. His explanation contained recent situations such as the progress of the validation and the evaluation of the test methods (the references 4 and 11), the making of the Web site of JaCVAM, the plan of taking part in the international organizations (the reference 10), the 7th World Congress on Alternatives and Animal Use in the Life Sciences, and the foundation of the Korean Center for the Validation of Alternative Methods (KoCVAM; the reference 3). The summary of the results of the activity for these four years was also introduced (the references 5, 6 and 12). Because the 5-year budget for JaCVAM will be finished at the end of this fiscal year, JaCVAM is busy to collect related data and files. He explained that this work resulted in unpleasant situations such as a trouble to the Advisory Council. JaCVAM is now reexamining its structure and applying the increase of staff and new budget. In addition, the validation and the evaluation by the third party get into difficulty because of the short of the number and the quality of cooperative persons and the budget (the reference 8). He explained that JaCVAM would like to appeal the cooperation among

ministries and government offices (the reference 9).

In the section of questions and answers, Dr. Ohno pointed out the mistakes in the explanation about the reexamination of the structure and the amount of the budget. Dr. Shono of the Advisor Council provided his opinion that the Japan Chemical Industry Association is able to prepare competitive budget for the development of alternative methods, but that it is difficult to solve the short of the experts in this area. For the cooperation among ministries and government offices, a continuous appeal to them may be necessary. The Ministry of Agriculture, Forestry and Fisheries seems to lack the recognition about international situations, and the explanation of the situations may be necessary. He also introduced the information that the foundation of another independent JaCVAM to correspond the results of the NEDO project is under consideration in the Ministry of Economy, Trade and Industry.

(Afterwards, Dr. Stokes pointed out that the year budget for ICCVAM shown in the reference is not 2.2 million Euro, but 2.7 million Euro. The ratios of the budget are ECVAM:ICCVAM:JaCVAM = 100:25:1.5. The budget of JaCVAM includes a Research Grant from MHLW).

4. Proposals for 3Rs in Japan

The following opinions were proposed from the members:

1) The importance of the education of students (mistakes in instruction guidelines and the short of instructors)
2) While the protection of wild animals is worth the preparation of the budget, only low public recognition is paid to experimental animals
3) The lobbyism to the Democratic Party of Japan from the industry (JPMA is now doing this).
4) The lack of awareness of the issues in ICCR as regulation authorities (hopes the discussion of the international harmonization of the alternative methods)
5) The necessity of the opportunities to appeal the indispensableness of experimental animals (including the necessity of studies using monkeys in some cases)

6) The serious attitude that cannot be utilized by the propaganda of the organizations for the prevention of cruelty to animals

Additional Remarks (from Dr. Kojima): I am very sorry for my misunderstanding about JaCVAM and its secretary office. The 5-year reexamination of the structure and the application of new staff are done for the Section for the Evaluation of the Novel Methods, and not related to JaCVAM. As I have repeated, JaCVAM is not an organization, but the activity mainly performed by the Section for the Evaluation of the Novel Methods based on the budget from MHLW. The budget applied is ad hoc to continue the activity of JaCVAM. I have never applied to found JaCVAM as a standing organization.