The Draft Minutes of the Proceedings of the 1st 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 (commonly called: The Advisory Council of JaCVAM)"

Date: March 5th, 2009 (Thursday); 15:00 to 17:00
Place: The Second Meeting Room, National Institute of Health Sciences
Attendants: Hiroshi Ono (Food and Drug Safety Center Hatano Research Institute Japan), Hiroyoshi Ninomiya (Azabu University), Takatoshi Kuhara (Juntendo University), Fumio Sagami (Eisai), Tsunehiko Iwai (Shiseido), Jun Washida (the Ministry of Health, Welfare and Labour: substitution for Toshiro Nakagaki of the Advisory Council)
Chairperson: Yasuo Ohno
Observers: Tohru Inoue (the Head of the Steering Committee), Mitsuteru Masuda, Yoshiki Tokura, Hiroshi Itagaki, Hajime Kojima

(The persons above are listed in no particular order and their titles are omitted.)

Discussion topics
According to the regulation of the administration of JaCVAM, Dr. Ohno of the Steering Committee chaired the meeting. Dr. Ohno apologized for the inadequate preparation of the appointment letters and contact with the members for this meeting. Because some members of the Advisory Council took up the post for the first time, all the members introduced themselves.

1. Confirmation of the minutes of the previous proceedings
Dr. Ohno asked about the minutes of the previous proceedings, but there was no special opinion.

2. The activity of JaCVAM and its plans for future
Dr. Kojima of the Steering Committee explained the recent activity of

JaCVAM and the methods in charge at present using the references 3, 4, 14, 15 and 16. In addition, using the reference 17, he introduced the progress of the Web site of JacVAM. In the section of questions and answers, Dr. Kojima explained about the following questions.

1) Relation between the Web site of JaCVAM and that of the National Institute of Health Science (NIHS)

Their URLs were placed in different locations. This is because the most of the Web site of JaCVAM will be highly possible to put special emphasis on the restricted part to upload the documents of meetings or similar ones, and their natures are not suitable for the Web site of NIHS.

2) Reasons for mostly investigating the alternative methods

The reason is, while paying an attention to the methods made in Japan, to introduce a large set of methods based on the mechanisms of effects and the physical properties of test compounds. As the methods made in Japan, the explanations were made for the phototoxicity test using yeast and red blood cells and STE (Short Time Exposure) assay for eye irritation testing. In this regard, Dr. Ono of the Advisory Council suggested that, at present, when a new method is proposed, the guideline document explaining how to use it is simultaneously prepared.

3) How to treat with the regulations of cosmetics

Dr. Kojima reported that JaCVAM was able to cope with the 2009 regulations of EU, which were proposed for the skin irritation test as alternative methods, but was not in time for the eye irritation test. He explained that JaCVAM will try to collect information in ESAC meeting shown in the reference 12. Dr. Iwai of the Advisory Council showed information that the regulations of EU are approaching, but the regulations are not applicable to administrative lows outside of EU. He provided his view that, though the industry needs to prepare for the regulations, animal experiments are sufficient at present for quasi-drugs.

3. Proposals for JaCVAM

Dr. Kojima explained the results of the activity of JaCVAM using the reference 18 and the references 5 to 11 and 13. In the section of questions

and answers, the following questions were raised, and the opinions were exchanged.

1) Relationship to ICATM

Dr. Ohno, the chairperson, explained that NIHS is planning to cooperate with ICATM in consultation with the Ministry of Health, Labour and Welfare (MHLW). However, the budget for the cooperation has not been decided, and the cooperation will be done within the possible extent.

Dr. Kojima explained that, to found a solid peer review consist of experts to cope with ICATM, not only the support from the Japanese Society for Alternative to Animal Experiments, but also the support from the Science Council of Japan and the Japanese Society of Toxicology. Although there were opposite opinions such as only a small number of experts of Toxicology in Japan, and the question on the recruitment of basic researchers to the peer review, Dr. Inoue provided his view as a Steering Committee's one that, because the Science Council of Japan proposed the enhancement of 3Rs of animal experiments, we should continue to require the Science Council of Japan of the cooperation through the proper routes such as MHLW and NIHS. He continued that the cooperation of basic researchers is in agreement with the principle of the Council for Science and Technology Policy, a governmental consultative body, namely, how science should be in the business structure, and this system of the cooperation of basic researchers, which is a matter of course in US, should be introduced also in Japan. In response to this, Dr. Ohno will owe to appeal to the Science Council of Japan as opportunity permits.

As for the budget, Dr. Inoue explained the view of the Steering Committee as the chairperson of it that the management of JaCVAM needs to find some way because the National Institutes cannot receive donations or entrusted research budgets. Dr. Ohno explained that this matter is also under consideration in NIHS.

2) Cooperation to the Korean Center for the Validation of Alternative Methods (KoCVAM)

Using the references 15, Dr. Kojima explained the situation of Korea. KoCVAM will be founded within this year, and the cooperation of JaCVAM to

this Korean organization is required. The opinions on how to treat it were questioned.
From the actual situation of the Korean organizations and the experiences in international meetings and cooperative studies, a number of merits and demerits were proposed from the members of the Advisory Council and the Steering Committee. In conclusion, the view that the cooperation is restricted to the exchange of information and practical cooperative works are avoided was regarded appropriate and was agreed.

The list of references distributed:

1) The minutes of the proceedings of the 4th JaCVAM Advisory Council meeting in the fiscal year from 2007 to 2008 (in Japanese)
2) The list of members of the JaCVAM Advisory Council, the Regulatory Acceptance Board and the Steering Committee (in Japanese)
3) The activity of JaCVAM from 2007 to 2008 and its plans in future (in Japanese)
4) The progress of the development of methods to which JaCVAM contributes (in Japanese)
5) Domestic and international the committees for validation or the third party evaluation committees which the Section for the Evaluation of the Novel Methods organizes or cooperates with in order to make the alternative methods official (the organizations for which the budgets are applied) (in Japanese)
6) The documents of the proposal of novel methods:
   The method alternative to the corrosion test
   The method alternative to the skin sensitization test (LLNA-DA method) (in Japanese)
7) OECD SPSF Non-radioisotope version of the Local Lymph Node Assay
8) OECD SPSF In vitro human epidermal model to assess skin irritation: LabCyte EPI-MODEL24
9) OECD SPSF Comet Assay in Genotoxicity Testing
10) SPSF and Supporting information
11) Draft Agenda WNT 21

12) 30th ESAC meeting

13) Draft Memorandum of Cooperation

14) 7th World Congress

15) 2009 Winter Conference of KSAAE

16) The 2nd Workshop of JaCVAM (in Japanese)

17) The Website of JaCVAM (in Japanese)

18) The activity of JaCVAM and its results for these four years (in Japanese)