The Draft Minutes of the Proceedings of the 4th Meeting (in the fiscal year from 2007 to 2008) 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: July 8th, 2008 (Tuesday); 15:00 to 17:00
Place: The First Meeting Room, National Institute of Health Sciences
Attendants: Hiroshi Ono, Fumio Sagami, Keiko Yamazaki, Jun Washida (substitution for Nakagaki of the Advisory Council), Hiroshi Itagaki (substitution for Iwai of the Advisory Council)
Chairperson: Yasuo Ohno
Observers: Tohru Inoue, Kenichi Nakazawa, Mitsuteru Masuda, Hajime Kojima

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

1. Confirmation of the minutes of the previous proceedings
Following the opening address of Dr. Ohno of the Steering Committee, the discussion of the topics started chaired by Dr. Ohno. Using the list of the members of the Advisory Council shown in the reference 2, it was announced that the representative of the Japan Cosmetic Industry Association was changed from Dr. Nakamura to Dr. Iwai. The minutes of the proceedings of the 3rd meeting shown in the reference 1 were confirmed, and there was no opinion requesting modification.

2. The activity of JaCVAM since February, 2008 and plans in future
Using the references 3 to 9, Dr. Kojima induced the contents of the activity of JaCVAM since February, 2008. The presentations of JaCVAM including those reported in the society meetings performed from WC6 follow-up symposium in February till the annual meeting of the Japanese Society of Toxicology in June were explained. In the following section of questions and

answers, Dr. Ono of the Advisory Council introduced the information that, as for the modified LLNA-DA method, the cell counting method is examined in Europe. Dr. Kojima explained that the agreement is necessary to determine which country prepares SPSFs to reflect the methods including LLNA-DA and BrdU in the OECD guideline.

3. International movements

Dr. Kojima explained the movements of OECD using the references 10 to 12, the movements of ECVAM and ICCVAM using the references 14 to 20, and the movements of JaCVAM introduced abroad using the references 13 and 21. For the drafts for the DECD guidelines related to the evaluation of safety of cosmetics, the expectation that public comments are now invited for skin irritation and will be soon invited for the method for eye irritation was introduced.

In the following section of questions and answers, Dr. Ohno of the Steering Committee asked about the evaluation of the Pyrogen screening. To this question, Dr. Kojima answered that the in vitro methods evaluated in Europe and US will be evaluated also in Japan. Dr. Ono expressed his opinion that validations nowadays are changing from scientific to political, and Dr. Kojima agreed to this. Dr. Itagaki of a substituted member of the Advisory Council introduced the article of New York Times criticizing ICCVAM, and asked how recent responses of ICCVAM are. Dr. Kojima explained the situation that this issue was not discussed in SACATM, but the activity of the working group increases compared with before. Dr. Ohno requested to obtain this article for Dr. Itagaki.

4. The activity of JaCVAM in future

Dr. Kojima explained the problems of JaCVAM in coping with international movements using the reference 24. The exchange of opinions was made on the matters that JaCVAM is activity and no official organization exists in Japan, and that the insufficiency of the budget. Dr. Yamazaki of the Advisory Council told that he is continuing lobby diplomacy for the modification of the Low against Cruelty to Animal Act in 2010, and

expressed his view of the difficulty to make a new low applicable budget for JaCVAM: to establish an organization under a new low is impossible. Other proposals including the possibility of a corporate body based on the selected corporation system of the Ministry of Heath, Welfare and Labour, and the possibility of the transfer to the Food and Drug Safety Center and Research Institute were presented. However, another opinion was also proposed, in which the importance is that JaCVAM is under the government, if considering previous activity and the way of thinking of cooperative persons. The exchange of opinions was also made on the restriction of the activity of JaCVAM within the area controlled by the Ministry of Health, Welfare and Labour. Dr. Inoue of the Steering Committee provided his opinion that, even if vertically divided, JaCVAM should be founded under the Ministry of Economy, Trade and Industry or other ministries. Dr. Ohno expressed his view that the duty of JaCVAM is the evaluation of safety studies, and JaCVAM is ideally placed under the Ministry of Heath, Welfare and Labour for helpfulness because the aim is different from other ministries.

As for the budget, Dr. Kojima insisted that the budget is necessary to cooperate with ICATM (the international cooperative organization for the alternative methods) at least, though the budget is smaller compared with Europe or US because of social necessity of 3Rs in these countries. To this insistence, the opinions that a corporate body can receive donations, and that, even if a government organization, it is possible to offer donations from foundations were proposed. Dr. Ohno expressed his opinion that it is possible to cope if all the governmental budget presently obtained in relation to JaCVAM is transferred to the budget for ICATM. Dr. Inoue criticized that, as a practical problem, the budget to attend the conferences of international organizations including OECD, ICH, WHO, JCCFA and IPCS is not supplied from the Ministry of Health, Welfare and Labour and is managed from the Grants-in-Aid for Scientific Research: we should face up to the reality. He explained that the budget may be supplied if an effort to obtain a letter of request for each cooperation with ICTM is continued.

5. Others

Dr. Kojima introduced the proposer and the evaluation report of the alternative method for escharotic test shown in the references 22 and 23. Dr. Ohno expressed his opinion that it is planned to submit to the Section for Safety of Chemicals, the Ministry of Heath, Welfare and Labour, and asked Dr. Washida of a substituted member of the Advisory Council the consideration on the best section of the Ministry to treat in future.
The term of office of the members of the Advisory Committee ends the last of 2008. The probable members after 2009 will be selected in the meeting of the Steering Committee. Dr. Ohno asked the present members of the Advisory Council for continuous cooperation because the larger part of the members will remain.

The references distributed:

1. The minutes of the proceedings of the 3rd meeting (in Japanese)
2. The List of the members of the Advisory Council (in Japanese)
3. The activity of JaCVAM from 2007 to 2009 and plans in future (in Japanese)
4. WC6 follow-up symposium (in Japanese)
5. INDEPENDENT SCENTIFIC PEER REVIIEW PANEL REPORT, May 2008
6. The 1st workshop of JaCVAM (in Japanese)
7. The abstract of presentation in SOT, 2008 (in Japanese)
8. The abstract of presentation in World Congress on in vitro Biology (in Japanese)
9. The abstract of presentation in the Annual Meeting of the Japanese Society of Toxicology (in Japanese)
10. OECD TEST GUIDELINES PROGAM, Standards Project Submission Form, Comet assay in genotoxicity testing
11. Updated work plan for the test guideline programme (TGP)
12. DRAFT SUMMARY RECORD OF THE 20TH MEETING OF THE WORKING GROUP OF NATIONAL COORDINATIONS OF THE TEST GUIDELINES PROGRAMME
13. JaCVAM update (the manuscripts of presentation in ESAC and

SACATM)

14. Proposal for International Cooperation on Alternative Testing Methods
15. ECVAM update
16. NICEATM-ICCVAM update on projects of joint interest
17. NICEATM-ICCVAM update
18. U.S. Acceptance of Alternative Methods, 1998-2008
19. Toxicological endpoints for which methods are ready before 2009 and 2013
20. International Collaboration update
21. Validations in Japan: how fur the third persons contribute to the evaluation (in Japanese)
22. The proposal form of a novel method (in Japanese)
23. The evaluation report of the alternative method for skin corrosion test (in Japanese)
24. The relations among validation studies, the international movements concerning the evaluation of the third persons, and JaCVAM (in Japanese)