VICH/04/075
18 January 2005
Final

VICH STEERING COMMITTEE
15th meeting
October 19-20, 2004
Berlin

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

Dr R. Kroker, chairman, opened the meeting by welcoming the participants to Berlin on behalf of the European Commission, EMEA and IFAH-Europe. He introduced Dr A. Gautrais, representative of the European Commission, who is the new VICH SC member replacing Mr.P.Brunet. She presented the apologies of Mr P. Brunet and explained that on short notice he was changing position in the European Commission.
The secretariat received also apologies from Dr K. McClure (AHI) who will not participate in future SC meetings any more and is replaced by Dr R. Livingston.

2. Adoption of the agenda

The EU proposed to add item "4.3 Discussions on the working practices of EWGs".
The agenda was adopted without further change.

3. VICH Phase II: 2006-2010

3.1 Feedback from the 2nd VICH Task Force meeting

The OIE representative, Dr P. Dehaumont, chairman of the Task Force (TF) summarised the work achieved by the TF at its 2nd meeting (*see presentation attached*) and introduced the proposed revised strategy and revised organisational charter.
The participants thanked the chairman and the members of the TF for the efforts achieved in producing and revising these documents.

3.2 Review of the Task Force proposal for a VICH Strategy

The SC reviewed the document "The Future of VICH: Proposal for a Strategy Phase II 2006-2010" (VICH/04/011, Draft 5) thoroughly and agreed on a number of clarifications and changes. One main element was the removal of redundancies of the text with wide parts of the "Organisational Charter of VICH", and it was agreed that the strategy document should focus on new elements and that all methodological aspects should be part of the Organisational Charter. The secretariat produced a new version of the document (draft 6)

which was discussed at the end of the meeting. The strategy document should be adopted by written procedure before December 20, 2004.

3.3 Review of the revised Organisational Charter

The SC reviewed the document (VICH/96/002, rev.8, draft1) in the light of the revised strategy document and discussed a number of amendments.

Concerning the periodicity of SC meeting, JMAFF informed SC that it favoured one meeting per year instead of up to 2 meetings per year.

The secretariat will circulate the document for a final revision by written procedure and adoption before December 20, 2004. The EU insisted that IFAH-Europe should clarify its legal entity before it could sign off the revised Charter.
(*Post-meeting note: The deadline for both documents has been extended to January 14, 2005)*

4. Review and adoption of VICH Guidance and Policy documents

4.1 & 4.2 Documents with amendments and for review

The participants reviewed the amended documents (SOP on VICH procedure for Working Groups Policy for disbanding Working Groups, Policy on consultation at step 4) presented by the secretariat.
After a brief discussion it was agreed to review these documents by written procedure after the final adoption of the VICH strategy and Organisational Charter.
The secretariat will circulate the proposed revised documents by January 15, 2005.
The secretariat will also circulate the proposed revised document on the production of a concept paper.

4.3 Discussion on the working practices of EWGs

The SC discussed, further to the EU proposal, on how working practices and the interaction between SC and EWGs could be improved to better achieve that the EWGs fulfil the targets set by the SC.

During the discussion the SC recognised that adequate guidance would be available in the VICH Guidance and Policy documents, and that it was often a matter of communication and of proper implementation of these SOPs.

The secretariat expressed its concern that it sometimes only had a very partial view of the flow of information from EWGs and suggested that the existing rules needed to be applied properly, rather than setting up further control points of EWG's activities.

~~After discussion, the SC agreed that the coordinators should request information from their regional experts every 2 months and pass it to the secretariat for circulation to the SC.~~

It was ~~also~~ agreed that a special session of the SC would take place at the 16th SC meeting in Washington, with all the topic leaders, to discuss with them the functioning and the objectives of the VICH process.

The secretariat was requested to set up a list of criteria and of dates for the future reporting by coordinators to secretariat. ~~The coordinators should send their suggestions to the secretariat by December 1, 2004.~~

JMAFF requested to discuss this item further at the 16th SC meeting.

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5. Progress reports of Expert Working Groups

5.1 Quality

The SC reviewed the written report prepared by the chairman of the Working Group, Dr K. Hamamoto, and presented by the JMAFF.
JMAFF confirmed that VICH draft GLs 39 & 40 were now in the public consultation period, which will end in January. The EWG will then be able to produce the step 5 document in early 2005.

With regard to the revision of VICH GL3 (stability), the FDA expert has drafted the first version of the revision, which has been distributed to the experts. All comments should be delivered by next November 5 and a revised draft will be prepared and circulated in order to produce a step 3 document in advance of the 16th SC meeting.

For the revision of VICH GLs 10 & 11 (impurities) the topic leader Dr Möller had circulated a draft document for comments by mid-October and the topic leader is already reviewing the comments received. It is also hoped that the step 3 documents will be available before the 16th SC meeting.

Dr Hamamoto expressed the wish to be able to hold a face-to-face meeting of the EWG at the VICH 3 meeting in Washington DC.

The SC congratulated Dr Hamamoto and the experts for the progresses achieved without needing to hold a full meeting.

JMAFF raised one issue regarding VICH draft GL 40: one comment already received pointed out that this GL does not specifically include Genetically Modified vaccines although the scope of the VICH GLs covers conventional vaccines
JMAFF pointed out that the view of the topic leader is that GL3 includes these Genetically Modified vaccines in its scope, but GL 40 doesn't. It is indeed clearly stated in chapter 3 of GL 40 that vaccines are excluded from the GL.
After discussion, the SC recognised that this statement may be misleading, and decided that the EWG should check the wording again.

The SC approved the 5th meeting of the Quality EWG to take place in Washington DC in May 2005, before the VICH3 conference.

The SC nevertheless encouraged the EWG to sign-off VICH revised GLs 3, 10 & 11 at step 2 by written procedure as soon as possible.

5.2. Target Animal Safety

The SC reviewed the written report prepared by the chairman of the Working Group, Dr T. Nagata, and presented by the JVPA.
During the first 2 days of the 7th meeting, held in Tokyo in September, the draft TAS GL for "pharmaceuticals" was discussed based on its draft 16, whilst the last 2 days were dedicated to the draft document "TAS GL for live and inactivated vaccines".

The draft GL 41 on reversion to virulence was signed-off at step 2 and presented to the SC for approval at step 3.
Much progress was also achieved on the TAS GL for live and inactivated vaccines, and draft 9 of the document was reviewed and a draft 10 was prepared for review by the next EWG meeting to be hopefully signed off at step 2. However, the number of animals to be used may still be an issue of concern at the 8th EWG meeting.

JVPA reported also that the draft GL on pharmaceuticals was expected to be progressed and signed off at step 2 at the 7th EWG meeting, but this was not achieved because FDA had raised additional comments during the meeting.
The main issues are the following:
- for safety testing FDA requires that 2 different multiples of the dosage have to be included in the studies, whereas Canada, the EU and Japan stated however that they would require only 1 multiple of the dosage;
- for the mammary gland safety testing for dry cow products, FDA requested to use dry cows for the GLP studies whereas the EWG had agreed that late lactating animals could be used.

Because of these additional comments at the meeting, the EWG could not reach an agreement. JVPA indicated however that the EWG will address all issues by mid-February and hopefully an agreement will be reached at next EWG meeting.
Dr Nagata asked to hold the 8th EWG meeting during 3 days in Washington DC on 23-25 May, and requested the presence of an additional expert from FDA.

The chairman thanked Dr Nagata for the excellent work achieved in this difficult scientific area.

JMAFF raised the problem of the number of animals used in the target animal studies, related to both pharmaceuticals and biologicals, and asked whether the GL could be split, with a lower number of animals for local market or the number left out in the GL. The concern would relate for example, to testing of horses, where it would be difficult in Japan to conduct studies involving e.g. 8 animals.

The SC felt that the number of test animals would be a technical issue to be discussed by the EWG. AHI proposed that a VICH GL gives requirements for all regions and should state the number of animals. However, at local level deviations could be allowed. If it would be left to the evaluation of a regional authority to accept lower criteria for products for the local market. Japan could accept this approach.

The EMEA pointed out that if the step 2 documents are only signed off at next EWG meeting, the EU would not be in a position to sign-off the draft GLs at the 16th SC meeting, but by written procedure after the 16th SC meeting or at the 17th SC meeting in fall 2005.

The SC approved the 8th meeting of the EWG to take place in Washington DC on May 23-25, 2005 and agreed that both FDA experts should attend the meeting.

5.3 Safety & Task Force on Microbial Safety

The SC reviewed the brief written report prepared by the chairman of the Working Group, Dr T. Mulligan and presented by FDA

VICH GLs 36 & 37 have just been approved by the FDA legal department and should be published for implementation soon

The public consultation process for the revised VICH GL 28 is finished in the EU and the USA, and Japan will publish the draft GL very soon.
No comments are expected and Dr Mulligan foresees that the GL will be adopted without change.
The EWG will then have completed its task.

JMAFF apologised for the delay in the publication and explained that a public consultation of this GL28 was under the responsibility of the Ministry of Health, Labour and Welfare, but JMAFF was asked to organise the public consultation. The public comments will be expected by December 31st.

The SC agreed that the step 5 document should be signed-off by the EWG before the end of January 2005 and that the SC would sign off the step 6 document before the end of February. The implementation date will be 1 year later.

5.4 Ecotoxicity and Environmental Impact Assessment

The topic leader, Dr J. De Knecht summarised, on behalf of the Chairman Dr J. Robinson, the work achieved by the EWG (*see presentation attached*) and highlighted the main steps of the decision-making process that led to the finalisation of both Ecotoxicity Guidelines (GL 6- Phase I and GL 38- Phase II).

The SC recognised that some clarifications will be needed, and that regional TGDs (Technical Guidance Document) providing further guidance will have to be established.
The EMEA reported that the work on TGDs had already started in the EU, because the implementation was more urgent than in other regions and proposed that the other regions may use the guidance that will be developed in Europe as basis for regional discussion.

JMAFF confirmed that both Ecotoxicity GLs will be implemented simultaneously in Japan and that regional guidance will be established.

Dr De Knecht pointed out the importance of all regions agreeing on tier A, although some differences may arise in the calculation on PEC because the biodegradation may be different in the different parts of the world. Therefore in some regions a product should go to the phase II, in others not.
During the discussion it was agreed that the GL 38 would be implemented within 1 year, except in Canada which is committed to adopting of Phases I and II Guidelines during the development of the new regulatory framework for assessment of environmental safety~~which aims for an implementation of phases I and II during 2006~~. The regions will do their utmost to prepare the relevant regional guidance documents within this timeframe.

The SC thanked Dr De Knecht and congratulated warmly the experts for their 9 years of hard work.

5.5 Pharmacovigilance

Dr I. Alexander (Health Canada) reminded the participants that the regulators had tried in April 2004 in Ottawa to find a way forward before the14th SC~~, in Ottawa,~~ and that a position paper had been presented to the SC for discussion. Members were asked to send their comments back to Canada and the secretariat by the end of last June.
At last SC meeting, Health Canada had also agreed to consolidate the comments received and produce a new document by mid-July for a second round of comments. Unfortunately, there has been only time for 1 round of comments and a new document was presented for comments at this SC meeting.

Dr Alexander indicated that the key outstanding issues are: the international birth date and timelines of reporting, third country reporting and definition of similar VMPs, standard terms and fields for electronic data reporting, the common dictionary and the pharmacovigilance information sharing between VICH regulators.

The chairman thanked Dr Alexander for the efforts made by Health Canada.

FDA believed that the EWG had struggled for the last 18 months because the SC had asked the technical experts to solve issues that were of political nature and therefore more appropriate for higher management, i.e. the interpretation of legislation and the flexibility of interpretation of existing laws. FDA called for flexibility with the different issues.

The EC expressed also its disappointment concerning lack of progress on this issue since the 13th VICH SC and this despite the meeting of the EWG in October 2003.

The chairman listed the outstanding issues and reviewed the current situation.
- *International birthdates*:
There is now agreement on this issue

- *Frequency of reporting*:
It is now agreed that it will be 6 months and multiples thereof.
The European Commission explained that the EU legislation had been amended recently and included now a provision that will allow the revision of PSUR frequency, after having gained experience.
In the EU, a PSUR is currently required at least every 6 months for the first 2 years, then each year for the next 2 years, then at the time of the first renewal and after at five –yearly intervals.
The New EU legislation - which will have to be implemented by 30 October 2005 at the latest - modified also the periodicity of PSUR as followed: at least 6 months for the first 2 years, then each year for the next 2 years, then at three-yearly intervals or immediately upon request.

JMAFF reported that in Japan the legislation requires that a new product be reevaluated after 6 years. However the MAH must provide a PSUR every year.

- *Definition of similar VMPs*
The chairman proposed to adopt the definition proposed by IFAH-Europe: "*At a minimum, any product would be the subject of reporting where it has a similar formulation (same active ingredients, same pharmaceutical form, similar excipients), the same route of administration (e.g. subcutaneous) and it is intended for similar use (incl, dosing regimens and rates, species and indication).*
After a thorough discussion, the SC adopted this definition.

- *Timing of the third country reporting*:

The current proposal is 15 days for expedited third country reporting.
The European Commission explained that this is fixed as such in the current EU legislation and in the new one (See above. Implementation date above- October 2005). The EC explained further that indeed it couldn't be easily changed as it necessitates to again go through a complete and long process of review of legislation which has just been recently completed. The EC informed the SC that the EC will look further at any possible room of flexibility in interpreting the rule of 15 days in practice. In particular, one would look further how it has been handled in ICH. The EU stressed that it is considered that the clock Start for third country adverse drug reaction should start when the AER for the product is known by the MAH in Europe, so that in practice the delay in reporting those third country reporting might be more than strictly 15 days from the original reporting in the third country. It was also repeated that within the EU, third country reporting concerns only human adverse reactions to VMPs, and SERIOUS adverse drug reactions to VMPs in animals.

During the discussion, the industry voiced strongly its concern because 15 days is very short to check the information, translate the report and adapt the cultural differences,
The SC asked the industry to express the concerns on the current proposal in writing to secretariat before December 20, 2004.

Then the regulatory authorities should by the end of February 2005 review the issues raised and discuss with their technical experts and their policy makers to find possible ways to address these issues.
The EU proposed, that, in case, the SC agrees to hold another meeting of the EWG, the regulators from the regions participate in the enlarged EWG in order to assist as necessary the EWG on the legal requirements within each region.

AHI suggested holding the meeting in May, just before VICH3.
FDA stressed that the conclusion to the outstanding issues will be brought at the eve of VICH3, and the risk of failure exists.

Meanwhile it was agreed that there should be an exchange of information and questions between all VICH parties, so that each SC member is able consult as many people as possible in preparation of the EWG meeting.

IFAH-Europe highlighted the need to receive a clear view of what has been agreed at this SC meeting, to sum up what is negotiable and to set up a clear agenda if the enlarged EWG meeting will be convened.

- *Fields for electronic data reporting*:
In absence of a full agreement of the other issues the electronic data reporting was not discussed. Canada pointed out that if the EWG would be reconvened it would have to reconfirm the outcome of its last meeting (October 2003) and only add a few fields that are considered critical and justified by different regions.

- *Next EWG meeting*
The EU recommended that meeting should have a very clear agenda, and that most issues should be solved before the meeting. It should also be the last EWG meeting.
The secretariat suggested to proceed as follows: first the industry has to identify its concerns on outstanding issues, and then regulatory authorities will have to respond as far as possible to these concerns. Only if and after that is complied, by the end of February 2005 at the latest, can the agenda of the EWG be defined.

The SC recognized that the normal VICH procedure requires the chairman of EWG to draft the agenda for the meeting, but the SC agreed that in this unique case the SC itself should draft the agenda.
FDA accepted to prepare a first draft and circulate it to the SC.

USDA voiced its concern about the timing of the process. Indeed, if by mid-February 2005, it appears that no agreement can be reached, a presentation should be prepared for VICH3 in accordance with the new VICH strategy.
USDA encouraged however strongly the participants to build on the consensus reached at this SC meeting. The EU expressed sharing views of USDA and recommended also to prepare a "contingency plan" in case no agreement can be reached, as the Pharmacovigilance topic needs to be addressed at the VICH3.

- *Conclusions and actions:*
Dr Alexander will complete the draft Ottawa Position Paper in accordance with the consensus reached at this SC meeting, and circulate the revised document by November 5. Then:

Step 1: Industry will provide comments highlighting problems and concerns to the secretariat before December 20, 2004.
Step 2: The regulatory authorities will try to find possible solutions by mid- February 2005
Only after that is possibly complied, a decision from the VICH SC for an EWG meeting in May would be made.

In case no agreement is reached, AHI required that the SC should approve beforehand what will be presented to the Conference.

5.6 Biologicals Quality Monitoring

The SC reviewed the written report prepared by the chairman of the Working Group, Dr O. Itoh, and presented by JMAFF.
The EWG did not meet since the last SC meeting. On the topic of test methods for mycoplasma, progress was difficult because of further delays in the preparation of reference strains by EDQM
On the extraneous agents topic, the EWG could make no progress and asks the SC for advice.

Mycoplasma testing
The EMEA reminded the participants that at the 14th SC meeting there had been an in depth discussion on possible approaches to make progress on the GL further to the EU proposal as to whether approval of the GL would be possible without testing the reference strains. The EU had explained that no new information on the reference strains would be available (information at 16th SC available in spring 2005) and that the SC had "recommended that the EWG should resume its work by discussing the best way to proceed under the direction of the topic leader and by providing a recommendation to the SC".

JMAFF replied that the experts were exploring the possibility of finalising the GL and nevertheless leaving out the strains until these will be available. Exchanges are ongoing in written form, but a meeting may be necessary in May 2005.

USDA confirmed that the EWG wished to meet in Washington DC. The experts hoped indeed to reach an agreement, because the concerns expressed last year were less important.
The EWG needs also to validate the fact that strains could be frozen rather than lyophilised, which would influence the requirements of the GL.

The SC therefore recommended that the EWG should revise the document taking into account the information currently available by written procedure, and consider developing the document without the reference strains.
If the EWG reaches an agreement, the SC could consider this agreement by written procedure.

On behalf of the industry, AHI expressed its concern that all participants would need to budget some costs to pay the EDQM for the reference strains.
If the regulatory authorities could purchase and distribute the frozen strains in the different regions, it would facilitate the approval of the GL.

Extraneous agents testing
JMAFF reminded the participants that at the previous SC meeting the upstream testing was reviewed and JMAFF started consequently to consider using the seed lot system.
JMAFF has however to set up the seed lot system with JVPA, and hopes therefore that EWG discussions will start next year.
As JMAFF will not be able to introduce the seed lot testing immediately, JMAFF requested that the downstream system should also be included in the GL.

The chairman pointed out that it was too early and suggested reviewing this issue again at the 16th or 17th SC meeting.

After discussion, the SC approved the 9th meeting of the BQM EWG only for discussion on Mycoplasma testing but recommended that it should be held in spring 2005, if possible in May 2005.

JMAFF informed the SC that as Dr Itoh's workload was very important, he would not be able to continue chairing the BQM EWG and requested therefore to step down as chairman, after March 2005.
JMAFF suggested therefore that Dr Nakamura would take the chair of this EWG. The SC agreed.

6. Adoption at step 3 and release of guidelines for consultation at step 4

GL 41 *- (Target Animal Safety) – Examination of Live Veterinary Vaccines in Target Animals for Absence of Reversion to Virulence*

The Steering Committee received the text of GL 41 as a proposed guideline at Step 3. This guideline was transmitted to the VICH members for a 6-month public consultation at Step 4.

The Steering Committee agreed that the deadline for members to submit comments on the guidelines is 25 April 2005.

7. Adoption at step 6 and release of guidelines for implementation at step 7

7.1 GL 28 *- (Safety: carcinogenicity) – Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing*

The SC agreed to sign off this GL 28 by written procedure, as soon as the consultation period in Japan will be ended.

7.2 GL 38 *- (Ecotoxicity Phase II) - "Environmental Impact Assessment for Veterinary Medicinal Products - Phase II Guidance"*

The Steering Committee adopted GL 38 as final VICH guideline at Step 6. This guideline was transmitted to the VICH members for implementation in the three regions at Step 7.

The Steering Committee agreed that the guidelines will enter into force by October 2005.

8. Update on the implementation of final VICH Guidelines since the 12th SC meeting in the 3 regions and the 2 observer countries

The EU reported no new implementation, as all the safety GLs have been introduced in the EU. The guidance document and notice to applicants regarding the establishment of maximum residue limits is currently being updated to take account of the VICH guidelines and will be finalised before the end of this year.

FDA reported that the safety GLs 36 & 37 have not been published yet, but will be very soon. All other GLs are published.

JMAFF reported no further implementation and confirmed that the consultation on GL 28 will be finalised before the end of the year.

ANZ reported no further implementation.

Canada confirmed that GLs 36 & 37 are published and that the revisions to the 5 safety GLs have been implemented.

The EU wished to inform the SC that for the residual solvent quality GL 18, both the human and veterinary scientific committees have agreed to add annexes to clarify the implementation of the GL in the EU. This has no impact on the text of the harmonised GL.

9. VICH3 Conference

9.1 Review of the final programme

AHI confirmed that the first announcement will be circulated shortly and that the final programme with the registration forms, hotels etc. should hopefully be ready by mid-January.

Dr Rick Hill will open the meeting on behalf of VICH and Dr Lester Crawford, acting FDA Commissioner, will welcome the participants and present introductory remarks.

Pedro Lichtinger, CEO of Pfizer kindly accepted to be the keynote speaker.

9.2 Guidance to the chairpersons

The EMEA recommended that the presentations should be interesting for the participants and should leave sufficient time for discussion.
Speakers should in particular present the decision-making process since the start which has led to the final Guidelines.

The SC reviewed the content of the Focus sessions:

Focus session A: Ecotoxicity: Dr J Robinson should present the overall process and Dr J. De Knecht the technical details;

Focus session B: Safety: FDA will chair and Dr Mulligan will be the speaker;

Focus session C: Quality: JMAFF will chair; the chairman and the topic leaders will discuss GLs 3, 10, 11, 39 & 40

Focus session D: BQM: AHI will chair and it was proposed that Dr K. McClure should present the topics;

The content of the session on Pharmacovigilance will depend on what will be achieved at that time; the SC confirmed the need of 1 authority's and 1 industry speaker;

Focus session E: TAS: JVPA will chair; the SC confirmed the topic leaders for biologicals and for pharmaceuticals, Dr Moos and Dr Nagata, should act as speakers;

Antimicrobial Resistance: Prof Kroker will chair, and Dr Mevius and Dr R. Bywater will act as speakers.

9.3 Organisational matters

The SC confirmed its wish to meet before VICH 3 and to hold a short meeting on Saturday morning May 28, after the Conference.

9.4 VICH 4

After a short discussion, the SC decided to add this topic to the agenda of the 16th SC meeting.

10. New topics

10.1. Review of the revised concept paper on Metabolism and Residue Kinetics

The SC reviewed the revised concept paper prepared by the EU.

The EU explained that the intention was not to determine withdrawal periods, but to define the tests to carry out for which the regions wished to define methods for the establishment of tolerance levels. Any duplication with the work done by other international bodies should absolutely be avoided

IFAH-Europe and AHI recognised the advantages of a harmonisation of the testing methods in the 3 regions. As currently there are different approaches towards methods and regulatory requirements in the regions, the SC would need to define clearly the scope of the EWG's task.

The EU confirmed that the scope was the data requirements only, not the calculation methods for ADIs, MRLs etc…. For the latter JECFA/Codex requirements already exist.

AHI believed that when the EWG will be formed, it should receive guidance on where to collect the information on the current existing regional and international requirements.

JMAFF repeated its reservations expressed at the last SC meeting and explained that in Japan this topic would concern the Food Safety Commission, the Ministry of Health, Labour and Welfare and JAMFF, which will have to work together.
JMAFF wished to limit the scope to new active ingredients only and to include 2 residue depletion studies (one radio- and one non radio-labeled study). JMAFF proposed to include target tissues as required in Japan such as liver, fat etc and injection site investigation …
JMAFF explained therefore that discussions would be necessary with the other 2 agencies before a definite support could be given.

FDA was still not clear whether they could commit and they would discuss further with AHI.

JMAFF will decide by December 20. Further to this, if an EWG were to be established Dr S Scheid from the EU was endorsed as topic leader and chairman.

Provided JMAFF confirmed Japan's support to the secretariat by December 20 at the latest, a feasibility study should be done based on an extended paper to be discussed by written procedure.

The SC finally agreed that the EWG would proceed in 2 steps: firstly it will be requested to draft a comprehensive paper clarifying the scope of the GL, establishing the existing methods in the different regions, pointing out the potential difficulties and evaluating the feasibility of the GL. Once all concerns will be clarified, the SC would authorise the EWG to draft a GL.

When the reply from JMAFF will be received, the secretariat will circulate a formal demand for the nomination of experts by the regions. Once the EWG is set up, the experts will have to establish by written procedure a proposed date for a first meeting of the EWG.

11. Review of VICH Workplan 2000-2005

The SC adopted the amendments proposed by the secretariat.

The SC agreed to set up a draft Workplan for 2006-2010 at the next meeting. Meanwhile the members will provide suggestions to the secretariat for new topics before the next meeting.

12. Any other business

None

13. Dates and venue of next meetings

- The 16th SC meeting will take place on 24-25 and 28 May 2005 in Washington DC (USA)
- The 17th SC meeting will take place on 1-2 November 2005 in Tokyo (Japan)

14. Adoption of the press release

The SC members reviewed and adopted the press release as proposed by the secretariat.

VICH STEERING COMMITTEE

15th meeting

October 19-20, 2004
Berlin, Europe

Chair: Dr R. Kroker, BVL

LIST OF PARTICIPANTS

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