Minutes of the Scientific Steering Committee Meeting of 14-15 September 2000

1. Welcome, apologies, introductory remarks, declaration of interest in relation to the current agenda

Prof.Dr.Pascal welcomed the participants. He apologised Profs. Dr. Kemper, Wierup and Kroes (for the whole meeting), Profs. Bridges and Hardy (for 14 September) and Prof. Gibney (for 15 September). The list of participants is attached as annex 1.

Introductory remarks:

Mr.Carsin, Director of SANCO-C, the directorate for scientific opinions informed the Committee of the Commission Decision on the Nomination of the new members of the SSC and thanked those, who do not return for a second period in office, for their contribution to the successful work of the SSC. He expressed the hope that they will continue to cooperate with the future SSC and the European Commission. The Chairman joined this position.

Declarations of interest:

No member declared an interest that could prevent him from participating in the discussion on any of the items on the meeting agenda.

2. Approval of the agenda

The agenda was approved with minor changes required due to partial absence of some members. The final agenda is attached as annex 2.

3. Approval of the minutes of the meeting of 06-07 July 2000

The minutes of the meeting of 06-07 July 2000 were adopted without changes.

4. Multidisciplinary matters:

a. "Emerging health issues"

After an intensive debate it was agreed to establish an overview of the emerging issues and to rank them according to their probability/urgency. Prof. Bridges will re-draft the introductory text to the list in line with the discussion held. It is envisaged to adopt an opinion on emerging health issues at the next meeting. Notwithstanding, the issue is a permanent one, meaning that also the forthcoming SSC should regular up-date the list and analyse if the Commission has to be made aware of a forthcoming issue.

b. "Emerging health issues: pilot exercise applied to GMOs"

The draft paper was extensively discussed and general agreement on the main conclusions was achieved. A revised version of the paper was distributed to all members for written comments and a finalised version will be tabled at the next meeting, for adoption.

c. Harmonisation of risk assessment procedures

Prof.Bridges, chairman of the Working Group, provided a detailed progress report. A final draft report is expected to be

submitted for adoption at the October meeting.

d. Safety of cotton (new question)

The SSC was asked to advice the Commission on how best to address a new interdisciplinary question regarding the safety of cotton products such as feminine hygiene products (e.g. tampons, sanitary pads etc), baby or adult incontinence products (e.g. nappies, etc), "medical cotton" product (cotton balls, make-up pads, gauze, etc) and cotton fabrics and garments.

After discussion it was agreed that Prof.Hardy would draft a short information note exploring the various multidisciplinary aspects of the question. This note will be discussed at the next meeting. It will then also be decided how the question will be addressed (e.g. as a multidisciplinary SSC working group, as a working group reporting to one of the Scientific Committees but with members from various SCs or as a single question attributed to one single Scientific Committee.)

5. Multidisciplinary matters relating to TSE/BSE

5.1. Report by the chairman of the TSE/BSE ad-hoc group

Prof. Gibney reported briefly on the meeting of the TSE/BSE *ad hoc* Group of 31 August 2000. All items addressed by the *ad hoc* group are further dealt with in detail under point 5.2 of these minutes.

5.2. Reports on specific issues:

- a. Recent declaration of Prof.Prusiner on BSE in sheep (July 2000) and
- b. Discussion on recently published research results on TSEs.

The SSC shared the view of the TSE/BSE ad-hoc group on these points. It agreed on the statement in annex 3 and to its pre-publication on the Internet.

c. Handling and storage of possibly BSE contaminated MBM

Prof.W.Bridges presented a brief account of the useful and numerous comments received so far, following the public consultation process via Internet that ended on 28 July. It is expected that a final document will be available for adoption by the SSC at its meeting of 22-23 October 2000.

- d. Quantitative risk assessment (vertebral column), and
- e. The use of ruminant-derived tallow in bovine feed, and
- f. The use of ruminant-derived tallow in milk replacers for calves, and
- g. Update of certain opinions (including on cross-contamination) in the light of the opinions on Human Exposure Risk and Infective Dose and Species Barrier.

The SSC followed the proposal of Prof. Vanbelle to jointly address these four items (5.2.d, e, f, and g) once all of them are mature enough, even if this requires postponing it to December 2000. However, the SSC expressed the hope to be able to finalise it in October 2000.

Geographical BSE-risk:

h. Update

Following the discussion at the last SSC-meeting 23 country reports and the final opinion were finalised and put on the Internet. The Czech Republic and the Slovak Republic were informed of the fact that their reports were not finalised.

In view of the SRM-decision (2000/418/EC of 29/6/2000) and the assumed need to assess, before April 2001, the GBR of many more Third Countries the SSC suggested a certain approach to this task. In line with this proposal the Commission decided to set-up a task force for that purpose, consisting of two internal and two external experts. The SSC was further informed that it was planned that the task force produces for each country a draft report, including requests for clarification or for additional information. After approval by the GBR-peer group the reports will be transmitted to the respective countries for comments. In view of the comments, and possibly a meeting of the task force with country experts, the reports will be finalised by the task force. After approval by the GBR-peer group, the finalised reports will be transmitted to the SSC for approval, probably in February/March 2001. A first batch might be ready for adoption earlier.

In preparing the new round of assessment a small group developed a new questionnaire that is intended to guide the applicant countries in providing their information and to ease the access of the assessors to that information. This questionnaire will be sent to all countries concerned by the SRM-Decision.

Efforts have been undertaken to identify all these countries and up-to 54 could still potentially ask for an assessment. Nine dossiers are already received and the other 45 countries will receive, soon after the SSC-meeting, an official letter from DG-SANCO. This letter informs them of the situation and invited them to provide a dossier before end October. A copy of the above-mentioned questionnaire is attached to the letter.

i. First case of BSE in a UK bovine born after 1 August 1996, and

j. Export from the UK of bone-in veal.

The SSC took account of the discussion held at the TSE/BSE ad-hoc group and the text proposed for the opinion on the UK-bone in veal. It concluded that indeed the case in question would not change its position that carcasses of 6-9 month old veal, that otherwise comply with all conditions of the DBES, do not pose a non-negligible risk for the consumer. However, on the basis of the available information it is not possible to conclude if the case results from maternal transmission or from feed. The SSC therefore underlined once more its concern that a case resulting from (cross-) contaminated feed born would put in question the assumed 100% efficiency of the 1996-ban. The adopted opinion on "export from the UK of bone-in veal" is attached as annex 4.

k. Update of the opinion of May 1999 on the evolution of the BSE-epidemic in the UK.

The SSC was informed on the progress made, which indicates that the decline of the epidemic is still in line with the scientific expectation, or even more profound. An opinion is expected for October 2000.

l. Pro-active opinion on risk scenarios, should BSE in sheep be found under natural conditions. Monitoring of research results on experimental BSE in small ruminants.

The SSC was informed on the progress made and agreed on the need to be prepared for the case that BSE would be confirmed in sheep under natural conditions. A report for discussion is expected for December 2000 or January 2001. The next meeting of the Working Group was scheduled for 26/09/2000.

m. TSE and culling

A draft opinion "BSE-related culling" was tabled, discussed and, after some amendments, adopted (see annex 5).

n. Origin of BSE and the "3 $^{\rm rd}$ route of transmission of BSE".

The SSC was informed that the working group met for the first time and agreed on an outline of its report, a work distribution between its members and on a work schedule. A report is expected for January 2001. The WG will not only address the various hypotheses on the origin of BSE but also on its transmission.

o. Alternative explanations for the origin of BSE: report to the SSC.

The SSC discussed briefly the proposed explanations and followed the suggestion of the TSE/BSE *ad hoc* group to invite the authors to provide solid scientific evidence before a further discussion of the issue would be sensible. The secretariat will send a corresponding letter to the authors.

p. Upcoming new questions

The SSC has been informed of the upcoming new questions outlined in annex 6. These questions will be forwarded to the TSE/BSE ad-hoc group as appropriate.

q. The discovery that blood of sheep experimentally infected with BSE but still being healthy (= about 1/2 into their incubation period), being able to transmit BSE to another sheep by the route of blood transfusion (*The Lancet*, 16 September 2000)

The SSC discussed the Houston *et al* communication that was published in *The Lancet* during the SSC meeting. Houston *et al* report on a finding that blood of sheep experimentally infected with BSE while still being healthy (= about 1/2 into their incubation period) did transmit BSE to one other sheep via blood transfusion.

The SSC decided to set-up a multi-disciplinary working group (WG) that should as soon as possible look into this matter. The WG should not only evaluate *The Lancet* paper but also collect additional scientific information that in the meantime became available on the subject and assess whether there is a need to revisit the blood-related scientific opinions of the SSC and of the SC-MPMD. If such need exists, then the WG should propose up-dates of these opinions. This might, however, need to be postponed until the full research results are available. The WG should also (urgently) obtain from MAFF what homologous experiments have been done in cattle (including the BSE pathogenesis experiments) and what the results tell us.

6. Organisational matters

No organisational matters were discussed.

7. Co-ordination: Reports of the Chairmen of the 8 Scientific Committees

The chairmen of all Scientific Committees provided written reports on the activities of their committees since the last SSC meeting (see annex 7)

8. Information by the Commission services on matters related to consumer health

DG RESEARCH informed the SSC of a conference of the co-ordinators of TSE-projects, funded under the European Framework Programme for RTD. All members of the SSC and the TSE/BSE *ad-hoc* group were invited to participate in the otherwise not public conference. A member of the SSC was looked for that could address the conference on Risk Assessment in the TSE-context.

The members were unhappy about the late information on this conference, that they find to be highly relevant to their work. However, it proved immensely difficult for them to make themselves available.

9. Any other business

The meeting ended on Friday 15 September 2000, at 16h00.

The next meeting will be held in Brussels, on 23/24 October 2000, starting at 10h00.

Annex 1: List of participants in the Scientific Steering Committee meeting on 14 - 15 September 2000

Members of the SSC:

Ing. Georges Bories, Prof. James W. Bridges (15 September only), Dr. Fulgencio Garrido Abellán, Prof. Michael Gibney (14 September only), Prof. Anthony R. Hardy (15 September only), Prof. Philip T. James, Dr. Keith H.Jones, *Prof. Fritz H.Kemper (excused)*, Prof. Werner Klein, Dr. Ib Knudsen, *Prof.Robert Kroes (excused)*, Prof. Albert Osterhaus, Prof. Gérard Pascal, Prof. Vittorio Silano, Prof. Marcel Vanbelle, *Prof. Martin Wierup (excused)*

Participants from the Commission:

DG SANCO:B. Carsin, P. Vossen, J.Kreysa, J.L. Jouve, J. Vergnettes, M. de Sola, G. Fracchia, F. Drion, A. Sanabria, G. Morrison, J.J.Rateau, M. Hotter, A. Klepsch, V.Van Haeperen

DG RTD: A. Luchetti, A. Di Giuilio

JRC: C. Von Holst

Annex 2: Agenda of the Scientific Steering Committee Meeting of 14-15 September 2000

- 1. Welcome, apologies, introductory remarks, declaration of interest.
- 2. Approval of the agenda.
- 3. Approval of the minutes of the meeting of 6-7 July 2000
- 4. Multidisciplinary matters:
- a. "Emerging health issues"
- b. "Emerging health issues: The case of genetically modified plants".
- c. Harmonisation of risk assessment procedures.
- d. Safety of cotton (new question).
- 5. Multidisciplinary matters relating to TSE/BSE
- 5.1. Report by the chairman of the TSE/BSE ad-hoc group
- 5.2. Reports on specific issues:

Recent issues that need discussion

- a. Recent declarations from Prof.Prusiner on BSE in sheep (July 2000);
- b. Discussion on recently published research results on TSEs.

Production systems and products.

- c. Handling and storage of possibly BSE contaminated MBM
- d. Quantitative risk assessment (vertebral column)
- c. The use of ruminant-derived tallow in bovine feed
- e. The use of ruminant-derived tallow in milk replacers for calves

f. Update of certain opinions (including on cross-contamination) in the light of the opinions on Human Exposure Risk and Infective Dose and Species Barrier

Geographical BSE-risk.

- g. Update
- h. First case of BSE in a UK bovine born after 1 August 1996
- i. Export from the UK of bone-in veal
- j. Update of the opinion of May 1999 on the evolution of the BSE epidemic in the UK.

Other issues:

- k. Pro-active opinion on risk scenarios, should BSE in sheep be found under natural conditions; monitoring of research results on experimental BSE in small ruminants.
- 1. TSE and culling
- m. Origin and transmission of BSE
- n. An alternative explanation for the origin of BSE: report to the SSC.
- o. Listing of upcoming new questions:
- -. Vertical transmission (survey protocols)
- -. Alternative means/methods of treatment of TSE risk materials: controlled use of SRM as fur animal feed; alternative heat/time/pressure conditions.
- 6. Organisational matters.
- 7. Co-ordination: Reports of the Chairmen of the 8 Scientific Committees
- 8. Information by the Commission services on matters related to consumer health
- 9. Any other business

Annex 3: Comments of the Scientific Steering Committee (SSC) on some TSE-issues that recently emerged in the scientific and popular press.

At its meeting of 14-15 September 2000, the SSC also discussed the following issues as a follow-up to the TSE/BSE *ad hoc* Group meeting of 31 August 2000.

1. A recent brief Communication in Nature (10 August 2000), suggests that, on average, no more than two cases of vCJD could arise from the consumption of one maximally infected bovine, as opposed to previous estimates that this number could exceed 100. This would result in a significant reduction of the expected maximum number of future vCJD cases.

The SSC noted that this short Communication contains quite limited scientific details and that the model leading to the results on which the conclusions are based, contains many assumptions. It noted that in an earlier publication of January 2000, the same research team accepted a much wider range of up to more than 100 vCJD cases that could arise from 1 maximally infected bovine. The assumption is made that only those with the presently observed susceptible genotype are at risk. Also, the communication does not take into account the most recent raise in numbers of vCJD cases. The SSC considers that in the field of TSEs there are still so many unknowns that it is very difficult to make predictions on

future numbers possibly to be expected, especially in this stage of the epidemic.

2. Prof.S.Prusiner's recent hypothesis (reported on in the Sunday Times of 23 July 2000) that BSE prions in sheep may have been there all the time at very low levels that pose no significant risk to humans but that unusual circumstances might have allowed them to spread either through the sheep or cattle population and accumulate to levels hazardous to humans.

The SSC noted the outcome of the e-consultation of Europe's main TSE experts organised by its secretariat in July 2000, which was in line with the final clarification provided on 2 August 2000 in a letter from Prof.Prusiner to the SSC Secretariat. BSE was not produce in mice by infecting them with material suffering from scrapie but both sheep scrapie and BSE prions had been transmitted to mice which are engineered to mimic cattle. From his findings Prusiner *et al* advance the *hypothetical* scenario that "it is possible that low levels of the BSE 'prion strain' are actually endemic in the scrapie sheep population, but that the BSE prions never surface as such because their presence is marked by the more rapidly growing sheep scrapie strain. Any unusual selective treatment, such as the change in rendering process, could remove the less dangerous sheep scrapie strain and allow the BSE strain to accumulate and spread to the cattle population". In conclusion, "BSE prions in sheep may thus have been there all the time at very low levels that pose no significant risk to humans but unusual circumstances might have allowed them to spread either through the sheep or cattle population and accumulate to levels hazardous to humans."

The SSC considered, as for the Collinge paper (see hereafter), that the Prusiner hypothesis in its present form (i.e., without published details) does presently not trigger the need for an immediate revision of the SSC's various "TSE in sheep" related opinions. It is, however, obvious that Prof.Prusiner's research and similar work by others, will be monitored carefully and, once finalised and published, further assessed by the Working Group presently carrying out a pro-active risk assessment for the case that BSE in sheep would be found under natural conditions.

3. The Hill *et al* publication (" *the Collinge paper*") in the Proceedings of the National Academy of Sciences (August 2000) on the possible presence of subclinical TSE infectivity in certain animals and its implications for the definition of cross-species barriers of TSE transmission.

The SSC considers that most of the scientific evidence on which the paper is based, was either known to it or anticipated by the SSC and has been appropriately addressed in various scientific opinions. As a matter of principle, the SSC has not based its risk assessments with regard to the safety of animals on results of end-point titrations with clinical disease in laboratory animals as the sole parameters. Furthermore, the SSC reviews and updates its existing opinions in the light of emerging scientific data, on regular basis. The relevance of 4 of the SSC opinions with regard to the Collinge-paper, is summarised in annex. The following incomplete list of SSC recommendations, can be presented as an example on how the possible existence of subclinical infections with important public health implications with relation to dietary exposure, have already been taken into account in the SSC opinions:

- **Product safety** (gelatine, tallow, meat-and-bone meal, dicalcium phosphate, ...): the opinions start from the hypothesis that an animal with TSE, but apparently healthy, would be slaughtered and assume *a very low species barrier*. The recommended production standards aim, when a TSE risk cannot be excluded, for safe sourcing of raw material, removal of SRMs and severe processing conditions.
- **Geographical risk**: a risk level is attributed to the ruminants of countries or regions where BSE might be present, even if no clinical case have been detected.
- **SRMs**: removal of the ruminant tissues with the expected highest infectivity levels, should they be slaughtered without a TSE having been diagnosed;
- No further use of **fallen stock** and certain animal categories, as a TSE could be at the basis of the death or could be [undiscovered] present in certain animals.
- Avoidance of **intra-species recycling** (see annex for details).

The SSC concluded that there is at present no need to revise its TSE-related opinions. It, however, asks its secretariat to

request from the UK and the EC research authorities the most up-to-date research results on TSEs in pigs, poultry and in fish. From an analysis of this info should appear whether there is a need to revisit certain opinions.

It also asks the TSE/BSE *ad hoc* Group to assess whether there is a need for an adaptation of TSE surveillance strategies in farmed animals and whether there is a need to update the opinion on breeding for scrapic resistant sheep as a means to control TSEs in small ruminants.

Attachment: The relevance of 4 SSC opinions with regard to the Collinge paper (August 2000).

The TSE/BSE *ad hoc* Group considers that most of the scientific evidence on which the paper is based, was either known to or anticipated by it and has been addressed in various scientific opinions. To be mentioned especially are:

- a. The Opinion of 24-25 June 1999 on The risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials.
- b. The opinion of 22-23 July 1999on the policy of breeding and genotyping of sheep, i.e. The issue of whether sheep should be bred to be resistant to scrapie.
- c. The opinion of 17 September 1999 on the risk born by recycling animal by-products as feed with regard to propagating TSE in non-ruminant farmed animals.
- d. The opinion of 13-14 April 2000 on Oral exposure of humans to the BSE agent: infective dose and species barrier. (Adopted following a public consultation via internet between 6 and 27 march 2000)

The **first opinion** considers the risk to the public, to animals and to the environment from transmissible biological and chemical agents which may be present in fallen stock and dead animals. The opinion makes recommendations on how such risks can be minimised. In the light of experience with BSE this includes consideration of unconventional and as yet unknown agents. The risk to man from dead animals and condemned materials is considered to depend on:

- The nature and level of the agent(s) present in the dead animal / fallen stock, which in turn relies on accurate diagnosis and measurement;
- The prospect of intra and interspecies transmission;
- The actual processing / disposal method used;
- The prospects of human exposure as a consequence of the processing / disposal.

Whilst also addressing zoo-, laboratory-, exotic- and pet animals, the opinion states, with respect to the susceptibility of pigs, poultry and fish to become infected with TSEs is concerned, that there is only evidence that pigs can become infected through intra-cerebral inoculation with infectious BSE material. To date no experiments have shown that pigs, poultry or fish could be infected with TSE *via* the oral route. Whilst recognising that experimental transmission *via* the i/c route has been shown for a number of animal species, the to date not proven hypothesis that orally TSE-inoculated non-ruminants without any signs of disease could carry the TSE-infection in their tissues has is considered unlikely.

The **second opinion** addresses, amongst other issue, that an animal not showing clinical signs can be infectious. It mentions the experimental evidence for the existence of hidden infectivity. It clarifies that "resistant" sheep may include animals that remain clinically free of scrapie *signs* for normal life-span but could still harbour the infectious agent, posing a threat by maintaining the infectious agent. It points at the possible existence, for sheep, of carrier animals with latent scrapie infection, that will not itself develop disease but with the ability to pass infection on to other sheep. This opinion also states that cross species persistence may also occur: hamster scrapie injected into mice does not produce disease but the hamster scrapie remains in brain and spleen of the mice and can be recovered in a form still able to infect hamsters. The SSC concludes, amongst others, that the possibility that sheep may harbour a latent scrapie

infection exists and if so, that they could pass an infection to other sheep.

The **third opinion**, on intra-species recycling, stated in mid 1999, that:

- "a. So far no scientific evidence exists to demonstrate the natural occurrence of TSE in farmed pigs, poultry and fish, which may create a basis for an intra-species progression of a TSE infection due to intra-species recycling.
- b. Given the limitations of the surveillance in certain areas, and the length of the incubation time in relation to the normal (=economic or commercial) life span of the animals, it can not be excluded that cases occur and that, perhaps more important, an undetected pool of infectivity is build up.
- c. Because of these two preceding points, the SSC wants to underline that in scientific terms absence of evidence is neitherevidence of absence nor of presence of a risk. However, it is impossible to exclude, on the basis of the available evidence, that TSEs are already present (albeit undetected) in non-ruminant farmed animals, in particular not if there is reason to assume that these species have been (and might still be) exposed to BSE-contaminated feed (produced from ruminants).
- d. Recycling of animal material, in general, will increase the risk that cases occur or undetected infectivity pools develop,in particular if potentially BSE (TSE) contaminated material is recycled to ruminants or (possibly) susceptible non-ruminants.
- e. Intra-species recycling will, due to the absence of a species barrier, increase the risk further.
- f. If recycling, and in particular intra-species recycling, of animal material to farmed animals can not be avoided, all measures that reduce the recycled infectivity would reduce the risk.
- g. Measures that reduce the recycled infectivity include:
- exposing the recycled animal material to a treatment by 133°/20'/3b or equivalent conditions,
- excluding those tissues known to carry the highest infectious load (SRM),
- excluding fallen stock from the production of feed,
- stop feeding pig, poultry or fish potentially contaminated feed a sufficiently long period of time before slaughter in order to reduce the risk of recycling infectivity via the gut-content.
- h. It has to be understood that
- the possible measures would not be able to reach a zero risk should infectivity enter the recycling loop, and
- that due to the long incubation time of this type of disease a significant risk would have build up before an incidence becomes visible (as has been seen in the case of BSE in the UK).
- i. The SSC considers R&D in the field of surveillance and (pre-clinical) diagnostic of TSEs and the experimental transmission of TSEs to farmed (non-ruminant) animals to be of highest priority."

The **fourth opinion** states, on species barrier: "The size of the species barrier for BSE-in-ruminants to BSE-in-humans is not known and may be large (for example a barrier of the order of 1000, as assumed in some risk assessments) or small. Given the conflicting scientific data and thus the uncertainties about the bovine-to-human species barrier as outlined in this document, the assumption of a worst case scenario considering no (=1) barrier should be included, although available evidence indicates that values greater than 1 are likely to be more realistic. The Working Group therefore recommends that, until more scientific data are available, for risk assessments of human exposure to potentially BSE contaminated products, a species barrier of about 1 should considered as a worst case scenario and that, in risk assessments, the range from 10 ⁴ to 10 ¹ is considered. The latter order of magnitude would imply that the

minimal infective dose value(s) considered/accepted to be valid for animals, should also be applied for humans."

Annex 4: Report and Scientific Opinion on: EXPORT FROM THE UK OF BONE-IN VEAL adopted by The Scientific Steering Committee at its meeting of: 14-15 September 2000 (Distributed separately)

Annex 5: Opinion of the Scientific Steering Committee on the BSE-related culling in Cattle adopted at the meeting of 14/15 September (Distributed separately)

Annex 6: Reports from the secretariats of Scientific Committees on the major activities and milestones since the SSC meeting of 6/7 July 2000.

Scientific Committee for Plants

At the Plenary meeting of 22 September, the following 4 opinions were adopted:

- 1. Opinion of the Scientific Committee on Plants regarding the evaluation of ethoxysulfuron in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market. (Preliminary opinion)
- 2. Opinion of the Scientific Committee on Plants regarding the evaluation of thiabendazole in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market.
- 3. Opinion of the Scientific Committee on Plants regarding the evaluation of a document concerning the FOCUS groundwater scenarios in the EU registration process.
- 4. Opinion on the submission for placing on the market genetically modified maize (*Zea maize*) Line GA 21 with tolerance to glyphosate, notified by Monsanto (notification C/ES/98/01).

Scientific Committee on Animal Nutrition (SCAN)

Working groups continued their work on the different questions currently submitted to the Committee. Some of them met in September.

For most of the feed additives under discussion, additional informations are requested from the Companies owning these products and pending receipt of answers, no adoption of report is expected.

Concerning more general questions like the one on dioxins, the ad'hoc Working Group is close to finalisation and the draft report is likely to be adopted by the Committee in October.

Scientific Committee Veterinary Measures relating to Public Health

The different working groups of the SCVPH continued their works and some of them finalised the drafts, which were discussed at the plenary meeting of September.

The SCVPH adopted a report on cysticercosis. Another report (on trichinella) has to be circulated for possible adoption by Written Procedure.

Scientific Committee on Animal Health and Animal Welfare

1. Animal Health

The subcommittee on animal health met on 27 September and approved two draft reports. The reports on Infectious Bovine Rhinotracheitis, a herpes virus and on the inactivation of viruses in blood will now be discussed in the next meeting of the Committee on 25 October, with a view to their adoption.

Other ongoing issues in Animal Health include a report on *brucella melitensis*, tests for contagious bovine pleuropneumonia, and transmission of fish disease agents though feed.

2. Animal Welfare

This subcommittee met on 26 September and reviewed progress on two extensive reports, which are currently being prepared in working groups. These concern the welfare of animals kept for fur production and the welfare of cattle farmed for beef production.

Both reports are expected to be completed early next year.

Scientific Committee for Toxicity, Ecotoxicity and the Environment

Since the last briefing on CSTEE's activities (included in the minutes of the SSC plenary meeting held in 6/7 July 2000) the 17 th and 18 th plenary meetings of the CSTEE took place respectively on the 5 th of September and 9 th of October 2000. In terms of progress made on the opinion requests submitted to the CSTEE and other CSTEE activities the following is of note:

- **A.** During the 17 th CSTEE plenary meeting, opinions were adopted on the following topics:
- 1. Methylene chloride and textile dyes.
- 2. BKH report "Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption".
- 3. Validation of testing methods for phthalate migration.
- 4. Cadmium in fertilisers Programme of procedures for the assessment of risk to health and the environment from cadmium in fertilisers.
- **B.** In conformity with the CSTEE opinion (adopted in 4 February 2000) on "Technical's for Guidance on Data requirements, version 4.3 December 1999, in support of Biocides Directive 98/8/EEC", a revision of the respective chapter 1, lines 412 to 449, took place and was presented to the CSTEE. This related essentially to the so-called "Waiving section". The CSTEE held the view that the changes introduced to that section were in conformity with the comments made by the committee in its opinion. This position was stated in the minutes of the September 2000 plenary meeting without a need for a formal new opinion to state it.
- **C.** Regarding **Regulation 793/93** no opinions on the respective Risk Assessment reports have been adopted since the SSC July 2000 plenary but the following ones are in the agenda of the 19 th CSTEE plenary:
- a) 1,4 Dioxane; b) 1,4 Dichlorobenzene; c) 4-Chloro-2-Methylphenol; d) Acetonitrile; e) Methacrylic acid; f) Acrylonitrile; g) Anisidine.
- **D.** On the subject "Terrestrial environment Available scientific approaches to assess the potential effects and risks of chemicals on terrestrial ecosystems" and after various submissions of a series of drafts the final one should be submitted and adopted at the next, 19 th, CSTEE plenary which is also the last one of the CSTEE before the new committee takes over. It is to be noted that a pre-final draft has been presented during the meeting of the Classification and Labelling working group (Directive 67/548) that took place in Ispra in September 2000, where it was welcomed.
- **E.** Activities continued on the topic "Exposure data in risk assessment" and a new topic ("Margins of safety") was started by the CSTEE; a working group was set up and met already once. This activity, like the one previously mentioned, is set to be continued by the next CSTEE.
- **F.** The CSTEE also started again the tackling of the subject *EU Water Framework Directive* since it was finally submitted the outstanding report "*Development of a specification for the intercalibration of biological monitoring methods Final Draft (European Commission Directorate General XI), Report No: CO 4751/1 October 1999". Two working group meetings will have taken place before the November 2000 plenary.*

- **G.** During the 18 th CSTEE plenary (9 October 2000) a new opinion request was submitted by Directorate General Environment of the Commission on the subject *Evaluation of sludge treatments for pathogen reduction*; a working group was also set up to address this subject.
- **H.** The next (19 th) CSTEE plenary meeting is due to take place on the 9 th of November 2000. The 1 st meeting of the new CSTEE (20 th plenary meeting) is scheduled for the 5 th of December 2000.

Scientific Committee for Cosmetics and Non-Food Products

Since the last SSC plenary meeting, four Working Party meetings took place, during which the following items were discussed:

- 1. Alternatives: The question of consumer exposure is very important for the risk assessment of ingredients. However it happens that data transmitted by Industry do not seem to be reliable and the worst case scenario must be considered. More problematic is the situation where consumers are exposed to ingredients through various types of products (cosmetics, food, household products etc.); this would request a global and not sector-related risk assessment. Presently the procedure to answer this situation is not well defined.
- 2. *Detergents*: Presently the legislation on detergents considers only environmental aspects but doesn't take into account health issues. The SCCNFP has initiated a reflection on the health risks (cutaneous effects) for consumers due to the use of detergents, on the identification of the responsible ingredients and on the need to inform consumers.
- 3. *Inventory*: The SCCNFP is considering the updating of Section II of the Inventory on perfume and aromatic raw materials. It is agreed that, in spite of the fact that the labelling of fragrance materials is not compulsory, the information given in the Inventory should be more transparent. The SCCNFP has presented proposals.
- 4. Preservatives, Colorants & Fragrances: the SCCNFP initiated the evaluation of fragrance materials which cosmetic products should not contain except subject to the restrictions and conditions laid down. Basis for this work is the IFRA list of restricted fragrance ingredients. Draft opinions were prepared on 2 polycyclic musks and addressed to the plenary meeting for adoption.

Scientific Committee for Medicinal Products and Medical Devices