

COST ACTION FA0804

Molecular farming: plants as a production platform for high value proteins

Minutes of the 5th Management Committee Meeting

Vico Equense (Naples), Italy, October 8th, 2010 at 14:00 o'clock

1. Welcome to participants

The Chair welcomed the participants and opened the meeting at 14 o'clock. The Agenda was delivered only a couple of days prior the meeting and the Chair apologised for that.

2. Adoption of the agenda

The agenda was adopted unanimously. The additional matters could be dealt in miscellaneous section.

3. Presentation of the delegations

Twenty four participants representing x countries were present (see annex 1).

4. Approval of the minutes of the previous MC meeting

The minutes of the previous MC meeting (held in Brussels on 17th June, 2010) were reviewed and accepted unanimously.

5. Greetings from the COST Office

Science Officer Ioanna Stavridou was not able to attend the meeting but she sent her greetings via the Chair. She especially encouraged people to apply for STSMs and ESR conference grants which are now available. STSM leader Tomas Vanek commented that travel costs and budgets for STSMs should be reasonable. The Chair reminded that there might be a possibility to apply for additional funds from the COST Office in case we show that our Action is very active.

The MC delivered the following greetings back to the Scientific Officer: There are some



concerns on the whole Grant Holder system and the MC saw it as a waste of money since GH system reduces the budget for the Action itself by 15%.

A question was raised concerning the reimbursement of the Rapporteur. The Chair clarified that such costs have to be covered by the Action (COST policy).

6. Status of the Action, including participating countries

i. Reports by the WG coordinators

WG1 (Paul Christou):

FG1 will be divided into two subgroups: FG1a) Open field crops-approval process for pharmaceuticals. Inge Broer, Maurice Moloney and Joachim Schiemann were chosen to act as FG1a co-leaders. FG1b) Contained use-approval process for pharmaceuticals. Heribert Warzecha was chosen to act as FG1b -leader and Vice Chair Julian Ma will communicate with John Butler (Bayer) in order to find another suitable FG1b co-leader candidate from the industry.

It was decided that Bart van Droogenbroeck takes over FG2. Udo Conrad kindly agreed to act as co-chair.

Julian Ma and Paul Christou will continue as leaders of FG3.

There is a need to nominate new FG4 leaders. Julian will talk to Harry Thangaraj and Ann Depicker will contact Jan Staelens from VIB. In addition, Niels Lowaars from Wageningen was considered as a possible candidate.

WG2 & WG3 (Stefan Schillberg and Dirk Bosch):

Stefan Schillberg and Paul Christou are in the process of finalizing special PMF topics for periodic pro-spective reviews in Transgenic Research. The plan is to publish a series of articles over the next 18 months. Stefan and Paul will approach possible contributors and it is considered essential to include established contributors from outside our Action. For example Ed Rybicki and Beth Hood are being considered as suitable authors. Stefan will circulate the outline among all MC members.

Arjen Schots and Dirk Bosch will lead the construction of the database which is already well advanced.

First version of the White paper is in process and the persons involved in writing at first stage are Stefan Schillberg, Dirk Bosch, Arjen Schots and Einar Mäntylä. After the core team has made the first outline they will ask for input from other participants.

ii. Short Term Scientific Missions (STSM)

There were nine concluded STSMs and two in progress. Tomas will provide further information to Bart to be included in the Action website. The presentations of finished STSMs will be postponed until the next annual meeting rather than including them in the WG1 workshop in Bulgaria (as had been decided earlier at the Brussels' MC meeting). The next meeting in Bulgaria (March 2011) will focus on WG1 issues entirely.

The Chair encouraged everybody to apply for new STSMs.

iii. Action Web site and the first leaflet

The first leaflet is now ready and 700 printed copies were made available during the meeting (20 leaflets per country + additional copies for the three WGs). These should be distributed appropriately to assure maximizing dissemination of The Action's activities and mission.

A double sided A4 leaflet will be created. This will be placed as a pdf on our web site and also will be given to Karin Metzloff (Executive Director of EPSO) to be put on EPSO web pages. The MC members will translate the leaflet into their respective languages to Bart within four weeks. All countries will then print their own leaflets (A4 format) according to their needs. It was decided not to translate the term - Molecular Farming. However, the definition should be translated to clarify the term in different languages. From the national translations last paragraph "Join us" will be removed and replaced by the contact information of the national MC members.

Anton Liaimer suggested having the same layout for the database as in the web site and the leaflet. This was agreed.

iv. Topics to EU's FP7 program

A small working group (Julian Ma, Stefan Schillberg, Paul Christou, Dirk Bosch, Arjen Schots, Bart van Drookenbroeck and the Chair) met in London in August to brainstorm and develop possible topics related to MF for upcoming EU Framework program(s). This resulted in five suggestions and these were presented during the current the meeting on October 7th, 2010, to all participants. These were also presented by the Chair in the General meeting of EPSO (Olos, Finland, August 29th, 2010). As a result of the Olos meeting, one of the topics - Synthetic Biology - was taken forward by EPSO as one suggestion to the KBBE work program. Julian will send these five topics to all Action members.

7. Working plan of the Action for the period 1.4.2010 – 31.3.2011

i. Budget status

The budget status will be clarified after all the costs of the annual meeting at Vico Equense have been balanced. This will determine the size of the WG1 meeting in Bulgaria, March 2011. It was commented that a minimum of 20-25 persons might be an appropriate number of participants (depending on budget constraints).

ii. Reimbursement practices

Because of the limited budget and higher number of participants than anticipated at the annual meeting in Vico Equense the MC discussed and agreed on changes in the reimbursements policy as follows: The 3rd night was reimbursed only for one MC member per country who participated the MC meeting and the hotel reimbursement will be based on real costs (MC decision 17th June, 2010). In addition it was requested that group leaders pay their students' costs and the Industrial Partners would also this time pay their own costs. The Chair had consulted Ioanna Stavridou on this matter and got the following information and advice: In some Actions Industry is even sponsoring the meetings and this way providing valuable financial support for the limited budget of the Action. However, if the meeting costs are higher than anticipated there are two ways to handle the situation: a) if the budget allows to reallocate money from another activity which has an allocated amount that has been under-spent or is foreseen not to be spent (e.g. from STSMs to meetings) or b) to apply a number of restrictions. For both cases an MC decision or at least a decision from the executive group is required. MC decided not to use STSM allocations but to apply a number of restrictions.

Regrettably, the restriction in reimbursements caused two individuals from industry to cancel their participation. These partners indicated that they will withdraw from the Action. As an action point Arjen Schots will speak with these partners to clarify the situation and stress the importance of Industrial Partner active participation in our Action. In addition, mutual benefits should be clarified. Industry is always welcome to join our Action and MC members were reminded to advertise our Action as broadly as possible.

iii. Action plan

- **How to reach the Deliverables**

WG leaders were asked to send the Chair within one week the Action plans (bullet points) put in place at the annual meeting and these will be incorporated to the minutes of the MC meeting.

WG1

Focus group 1-Regulatory framework

FG1 Regulatory Framework (chair Joachim Schiemann) will be divided into 2 subgroups

FG1-1 Regulatory Framework for contained use production of PMP and approval process for medicinal products (co-chairs Heribert Warzecha, NN – see Action point 5 below)

FG1-2 Regulatory Framework for open field production of PMP and approval process for medicinal products (co-chairs Inge Broer, Maurice Moloney)

Since the commercialization of medicinal or industrial products produced in the frame of experimental field releases is not allowed in Europe and placing on the market of the respective GM plants is very costly and not appropriate for most of the PMP/PMI applications, amendments of Directive 2001/18/EC are necessary to allow the commercialization of products from GM plants which are grown under conditions to be defined without the need of an authorization under Part C (placing on the market). Joachim Schiemann will provide a first draft to be illustrated by two examples: insulin production in safflower seeds and production of antimicrobial substances (Maurice Moloney and Julian Ma, respectively, will be asked to provide a short description of the advantages for Europe to produce these products under open field conditions). Instead of an open letter the channels suggested by Karin Metzloff to get the information to the right places in the Commission will be used.

Important milestones for open field PMP (PMI) production have been reached. The next milestone will be the improvement of the regulatory frame for the commercialization of biopharmaceuticals produced in GM plants under open field conditions.

Action points:

1. Bringing the necessity for reducing the regulatory burden for GM plants to the attention of an international audience and to provide suggestions – 11th ISBGMO, November 2011
2. Letter to the Commission on amending Directive 2001/18/EC, January 2011
3. Review / discussion paper for Transgenic Research on regulatory issues, 1 draft March 2011
4. Kick-off discussion to make the case for *trait-* rather than *event-* based regulations, including arrangements with “strategic partners”, Autumn 2011
5. Julian Ma will contact John Edward Butler-Ransohoff, Bayer Innovation, to suggest a co-chair)

Focus group 2-Public perception/stakeholder interactions

Bart van Droogenbroeck has taken over from George Sakelaris as FG leader, setting the stage for this FG. Udo Conrad volunteered to act as future co-chair of this FG. The revised website and the leaflet will be further developed to serve as tools to interact with potential stakeholders.

Action Points:

1. Initiate working group to prepare information package on MF to be used in secondary schools – targeted age of students: 15-18 years old.
2. Develop informative slideshow presentation that can be downloaded from our Action website for broad public - included in press kit on our Website
3. Organize stakeholder interviews - investigate possibilities to include MF questions in Eurobarometer
4. Identify and contact stakeholders that are willing to endorse a positive MF statement – open letter that could be sent to decision makers
5. Investigate possibility to realize MF promotional video that could be placed on YouTube

Focus group 3-Developing Country aspects

Action Points:

1. Initiate white paper on “Developing Country Aspects of Molecular Farming”.
2. Contact people in developing countries who are actively involved in Molecular Farming and establish a formal or informal link with them to co-develop strategic docs (such as the white paper) and also joint manuscripts for publication, joint events, etc.

Focus group 4-IP licensing strategy

This FG was not represented as the tentative FG leader or his replacement did not show up at the meeting. During the MC meeting it was agreed to nominate Harry Thangarat as FG leader. Ann Depicker agreed to contact VIB to investigate the possibility of one individual from that organization acting as co-chair for FG4.

WG2

Deliverable 1: Database

- See action points for WG3
- Records collected by WG3 will be complemented with MF papers from an additional Endnote library (if possible) (November)

Deliverable 2: Questionnaire on opinion of Molecular Farming

- See action points for WG3
- Review and evaluation of the already obtained questionnaires (December)

Deliverable 3: White paper

- See action points for WG3
- Preparation of the first outline (January)

Deliverable 4: Transgenic Research perspective articles

- Update author list (October)
- Define article format (November)
- Contact authors (December)

Deliverable 5: Next WG2/WG3 meeting

- Support organisation of the next WG2/WG3 meeting in Poland (Agnieszka Sirko has to confirm that the meeting can be held in Poland in March/April)

WG3

Deliverable 1: Database

The database is well on its way. The following actions will be undertaken to finish this:

Actual Database; should be finished by the end of the year/beginning next year

- Minor addition to the Fields (Fusion Protein to “Protein Class”).
- Help text will be provided by Dirk and Arjen
- Lay-out of database will be improved
- Improved Plot function will be implemented (if possible)

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Filling of the database

- 476 existing records will be complemented with those collected by Stefan Schillberg (if possible). (November: Action Stefan)
- Record will be distributed to COST members to help filling the database (First half next year)

Discuss and organize access to the database at next meeting.

Deliverable 2: Questionnaire on opinion of Molecular Farming

- Reviewing already obtained questionnaires (December)
- Re-formulating the questionnaire (if necessary) (January)
- Send questionnaire to all members and collect (February-March)
- Collect and process data: June

Deliverable 3: White paper

- Outline prepared by WG2 + WG3 leaders: January 2011. Stefan will make a first outline
- Input from other members (January-June 2011)

• Publications on website-List update

The Chair commented that only a very small number of members had sent publication lists to Bart van Drookenbroeck. All MC members should collect two publication lists from Action participants of their respective countries and send them to Bart as soon as

possible. These lists should contain published PMF papers since 2009 and be categorized into: a) papers with minimum two Action participants from two different Action member institutes and COST acknowledgement; b) all other our Action related papers since 2009. These will be placed on the Action website.

Tomas Vanek pointed out that abstract books or other similar activities should be published from all meetings (preferably with ISBN number). It was decided that these documents will be placed in the Action web site. Before placing the Abstract book of the annual meeting in Vico Equence to web Teodoro Cardi will request permission from all corresponding authors. In the future submission of the abstract will be considered as permission to place it on the web. This will be indicated clearly on the abstract submission form.

Julian Ma suggested that COST Office should have an Archive of the websites of concluded Actions. The Chair will communicate this to Ioanna Stavridou.

- **Database, status and development**

The Questionnaire that was distributed during the annual meeting will be edited by Dirk Bosch and Arjen Schots based on input received during the course of the meeting. Subsequently the edited form will be sent to all Action participants for further input.

- **Lobbying activities for molecular farming i the context of upcoming EU FP programs**

MC considered Karin Metzloff's presentation very useful and her suggestion to form a small working group to approach the Health Program Director was accepted. This working group will consist of Karin, Rainer Fischer (IME), Heribert Warzecha and yet non-nominated persons recognized in the fields of Medicine (e.g. Franco Buonaguro?) and Nutrition (Cathie Martin?). It was decided that Julian Ma represents PMF and our Action in this working group. It was decided to communicate with Karin to classify the composition and role of this working group soonest possible. The actual meeting with Health Program Director should take place latest at the first week of November. After getting feedback from Health Program Director the already formulated four topics will be developed further. Additionally the idea is to formulate visions on PMF in general as well as on future of PMPs.

Funding possibilities from IMI (Innovative Medicine Initiative) were discussed. In Brussels there will be new IMI calls on 13th of October. Ann Depicker will find out who from our Belgian Action members could participate in this event. IMI is looking for new topics especially on cancer and infectious diseases. There might be a possibility for PMF as well. Rainer Fischer has been in contact with IMI earlier and Stefan Schillberg will discuss with him on how to proceed.

8. Status of Non-COST country participants

Ioanna Stavridou had informed the Action that India was accepted as a Non-COST

participant of our Action in the last Domain Committee meeting. The request of China will be considered during the November meeting. Australia still needs to fill in the official application forms. Ann Depicker will assist them to do so. There were no other applicants.

9. Place and date of future meetings

Next WG1 meeting will be arranged in Bulgaria. Ivan Minkov will act as a local organizer. Paul Christou will take the initiative to develop the program in consultation with other members of the Action.

Next annual meeting was planned to be arranged in Ghent, provisionally from the 29th of August to the beginning of September. One possibility is to link it with Arjen's suggestion to arrange a PhD summer school (training school). For this option also other sources for funding should be explored. Small committee for the summer school option was put in place: Arjen Schots, Kristiina Mäkinen, Ann Depicker and Anton Liaimer. One possible option could be to have plenary sessions in the mornings for all and then the workshop for the students and WG workshops for Action members in the afternoons as parallel sessions.

Future WG2 and 3 meetings were also discussed: Early 2012 (February – April) for maximum of 40 participants in Poland. Agnieszka Sirko will look for options for venue and the prices.

10. Miscellaneous

The Chair reminded all that according to the Action's MoU we have committed to arrange a larger conference which would be open to individuals outside the Action. A possible time for this could be in September - October 2012. We should look for the possibilities to have it as a joint meeting of another conference. However, our conference should be distinguishable from the Verona meeting on PMP (next June 2011). Funding possibilities (e.g. sponsors) should be investigated. A planning committee was put in place: Dirk Bosch, Loic Faye, Herta Steinkellner, Åke Strid and Agnieszka Sirko. The arrangements should be initiated by the beginning of the next year.

Jochen Kuhmlehn had informed the Chair that he had suggested a PMF book for Springer to be published within 2-3 years. He had required if this would be of interest for our Action. Arjen Schots pointed out that there is a need for a teaching book on the subject. He and Bart van Drookenbroeck are already preparing some teaching material. In addition, Loic Faye has already edited a special PMF issue in The Plant Biotechnology Journal, earlier in the year. The MC decided that we will not contribute to the book as an Action, but of course individual participants are encouraged to contribute if they wished. The Chair will get an official invitation and communicate the MC's

decision.

Tomas Vanek informed that GM-crop field trials can be arranged at reasonable costs in the Czech Republic.

Teodoro Cardi noted that WG descriptions were missing from our web. Stefan informed that short texts have been provided to Bart van Drookenbroeck and this is work in process.

It was decided that the reimbursement of the 3rd night at Hotel Aequa will be cancelled for those MC participants that did not attend the MC meeting (8th October, 2010).

11. Closing of the meeting

The Chair closed the meeting at 16.30. The next MC meeting will be arranged in connection with the next annual meeting in early autumn 2011 (date and place still to be confirmed).

Annex 1

List of participants

Name	Country
1. Basinskiene, Loreta	(LT)
2. Bellucci, Michele	(IT)
3. Bosch, Dirk	(NL)
4. Capell, Teresa	(ES)
5. Cardi, Teodoro	(IT)
6. Christou, Paul	(ES)
7. Depicker, Ann	(BE)
8. Faye, Loic	(FR)
9. Häkkinen, Suvi	(FI)
10. Iannaccone, Rina	(IT)
11. Liaimer, Anton	(NO)
12. Lomonosoff, George	(UK)
13. Ma, Julian	(UK)
14. Mäkinen, Kristiina	(FI)
15. Oksman-Caldentey, Kirsi-Marja	(FI)
16. Poggendorf, Iris	(CH)
17. Ritala, Anneli	(FI)
18. Schiemann, Joachim	(DE)
19. Schillberg, Stefan	(DE)
20. Schots, Arjen	(NL)
21. Sirko, Agnieszka	(PL)
22. Steinkellner, Herta	(AT)
23. Strid, Åke	(SE)
24. Vanek, Tomas	(CZ)