Cost Action FA0804 WG1 report from meeting in Lleida, Spain, May 2009

The first WG1 meeting was held in Lleida, Spain on the 27th and the 28th of May, 2009. Thirty members, including six local hosts (UdL) attended the meeting. The Agenda and list of participants are attached to this report. The aim of WG1 is to develop a medium and long term strategy for molecular farming in Europe with a global perspective. Paul Christou as WG1 leader and local host initiated the discussion by setting the stage for the meeting. Participants agreed formally that the implementation of WG1 activities will be through the formation of focus groups (comprising academic and industrial members) with expertise AND INTEREST in specific aspects of the Action. He then presented the Agenda which had been circulated earlier. It was formally agreed that the major task for the day was the constitution of the four focus groups agreed at the last meeting in Athens (March, 2009) and the establishment of a mechanism for gathering and compiling information which can then be utilized to inform the outputs of the WG, in putting together: position and information papers, strategic documents, vision paper(s) and activities and actions to inform other WGs.

The initial major output from WG1 will be a position report summarizing the global state of Molecular Farming and the position of European research within that global picture. This will lead to the development of a strategic vision document whose purpose will be to identify areas where European R&D effort can have the most significant and global impact, and set out a long term strategy detailing how such aims will be achieved. Ultimately, the strategic vision document will act as a guide for relevant EU bodies and scientists to find science-based information that will help to focus European efforts, reduce redundancy in research and development, identify impact areas to enhance European competitiveness and identify a dissemination strategy to maximize stakeholder awareness, public acceptance and support, and regulatory support for Molecular Farming in Europe and beyond.

It was agreed that the short term objectives of the focus groups will be:

- Nominate and subsequently confirm focus group leaders
- Constitute definitive membership list
- Select 2 short term objectives per focus group
- Define 2 measurable outputs
- Implement activities and apportion tasks among focus group members
- Identify and exploit synergies with WGs 2 & 3

Focus Group 1. Regulatory framework

Joachim Schiemann and Frans van Dalen were nominated as leader and vice-leader, respectively. The short term objectives proposed (subject to further discussions lead by FG leader and vice-leader) were:

1. Make scientific (and if possible socio-political) case to lower the regulatory burden for molecular farming, primarily in Europe but also in the US through linking up with similar ongoing initiatives in the US.
2. Draft position paper and agree dissemination options

As Joachim Schiemann was not present at the meeting, Paul Christou agreed to let him know about his nomination as FG leader. Frans van Dalen was present and he accepted the nomination. A lively discussion ensued which is briefly summarized below:
Possible targets for position paper should be regulators and politicians and we should aim to critique existing regulations using arguments which have not been used extensively in the past, i.e. economic benefits to the EU. Additional elements should be safety, distinction between risk identification and risk management, and other documents generated by organizations such as EFSA, etc.
Focus on a comparative analysis of regulation. This should raise the question of lower regulatory barriers in emerging economies, how this will unavoidably lead to lower also EU barriers when strategic technology positions are taken by emerging economies. This will have a negative impact on job creation in the EU (Diego Orzaez).
Stefan Schillberg indicated that it might be useful to generate a table listing the different steps of the regulatory framework. In the second row actions can be indicated to lower the regulatory burden, where appropriate. If required, we may also indicate actions that are required to provide additional knowledge to fill the gaps. However, the regulatory framework will be highly dependent on the production systems used to produce the pharmaceutical proteins. Therefore, we may focus only on specific production systems.
Tomas Vanek suggested putting together a list of MEPs who could be engaged in discussions on the severe constraints of the current EU regulatory framework and how this results in an unfair disadvantage for EU SMEs as only the big multinationals are able to go through the EU regulatory system.

Focus Group 2. Public perception/stakeholder interactions

George Sakelaris & Bart Van Droogenbroeck were nominated as leader and vice-leader, respectively (both present and accepted the nomination). George then made a presentation on methodology and existing guidance documents in Europe and elsewhere. The major issue to emerge from George's presentation and the subsequent discussion was that a crucial task for FG2 is to identify the most appropriate stakeholder(s). A number of views were expressed on this but the prevailing view was to target stakeholders who are not biased or have entrenched positions. It was generally agreed that to do otherwise will simply be counterproductive as such approaches have failed repeatedly in the past. Further issues discussed are listed below:

- Objective: Increase awareness and information
- Use online communication tolls such as: *http://www.agbiotechnet.com/index.asp*
- Make the public aware about use of transgenic plants for molecular farming; biosimilars as examples of drugs that are accepted. Both insulin and glucocerebrosidase are examples of biosimilars. These will reach the market following an unconventional regulatory PMP path in Canada and Israel respectively (Bart Van Droogenbroeck).
- Identify the stakeholder groups at the national level (Agnieszka Sirko and Margaret Korbin) involved in the relevant research –production-processing-exploitation chain (e.g. patients organizations, farmers, animal breeders). Development of interaction with patient groups that can be linked to existing mol farm products or proof-of-concept studies is very important.
- Deliverable – a positive declaration or endorsment of molecualr farming from stakeholders
- Another argument that can be used in communication is that MF products are safer, and produced in a natural way, sometimes replacing chemically synthesized molecules (Bart Van Droogenbroeck) .
- Reduction of expenses of social security could also be used (Declan Nolan)
- Molecular Farming questions will be included in the next Euro barometer survey and we should have a say in formulating the questions if possible (George Sakelaris to lead)
- Diego Orzaez suggested a potential tangible deliverable. Documentary video for educational/promotion purposes, bringing the view of scientist? Distribution: YouTube/ University courses. Might this be covered by the COST action? Also joint educational programs at seecondary and tertiary educational establishments.
- Jon Veramendi indicated that the format of questions/answers is quite attractive and facilitates the global comprehension of the reader. For example, documents from the German Academy of Sciences and the Spanish Biotechnology Society have used this structure successfully.

Focus Group 3. Developing country aspects

Julian Ma & Paul Christou were nominated as leader and vice-leader, respectively. Paul Christou accepted the nomination agreed to let Julian Ma know about his nomination as FG leader.

A possible short term objective was proposed: strategies to facilitate technology transfer and capacity building. This will be discussed further.
Fernando Ponz stated the following: different stages of development exist in different developing countries. In Latin America, for instance, it would not be sensible to develop the same strategy for Argentina, Chile, Brazil, or Mexico, countries with research institutes and universities ready to adapt and/or develop MF almost immediately,

compared to less-developed countries in Central America, for example. With the first group of countries, MF European policies can be developed that seek collaboration for implementation of technologies with specific goals. It is important to note that all these countries have quite tolerant attitudes towards genetic engineering, some being leaders in production globally. It is less clear what type of strategy could be developed in the other cases. Here, most likely training specialists from pre-existing R+D centers would be an almost mandatory first step. In all cases, project funding will be an issue, but that is an aspect to be dealt with later in the development of the strategies.

Other points discussed:

- Consider developing countries as production sites
- Which regions will be considered as developing countries? Proposal not to include China and India which are booming economies, but rather focus on Latin-America and Sub-Saharan Africa
- Define benefits to the Action by having a FG on developing countries. Overlap with WG3; some examples of the organizations dealing with developing countries which we might approach: (i) Bill Gates Foundation; (ii) European Action on Global Life Sciences *http://www.efb-central.org/eagles/*

Focus Group 4. IP licensing strategy

Kirsi Marja Oksman agreed to contact an appropriate individual from VIB, Gent with expertise in IP licensing to serve as focus group leader. Antonio Molina was nominated as vice leader. Paul Christou agreed to contact Antonio (subsequently accepted nomination).

- Stefan Schillberg stated that it will be impossible to establish plant production systems without infringing IP generated by third parties. Therefore, an overview of patents and patent applications might be helpful to discuss potential licensing strategies. Similar to FG1 we focus only on specific production systems because this exercise will be pretty time-consuming.

Key points from discussion:

- Protecting inventions from an academic point of view
- Looking for collaborations, licensing opportunities etc from an industrial point of view. What is the value of an invention?
- Chris De Jonghe (VIB HQ, Belgium) will be invited to participate in future discussion to give input.

General comments:

1. WG1 needs a strong link with WG2 and 3 because regulatory frameworks, public perception, developing country aspects and IP licensing strategies heavily depend on the system that will be used for the production of pharmaceutical proteins (Stefan Schillberg and others).
2. We still need a good example demonstrating the advantage of plant-based production. So far, nobody has actually demonstrated that production of a specific protein is advantageous to production in for example conventional systems. Also arguments that we will face a lot of new product candidates are rather weak since many candidates fail within the first phases of development (Stefan Schillberg, Declan Nolan and others).
3. Andreas Voloudakis indicated that he will contact Kirsi and Tomas to propose a link between our Action and the one he chairs on transient expression systems.

Action points: To be developed through consultation with FG leaders and other members of the Action.

Paul Christou
WG1 leader

Kirsi-Marja Oksman
Action Chair