

Biofuelwatch response to the Consultation on the “Updated report and synthesis of views in response to paragraph 7(b) of decision XII/24” and the “Report of the meeting of the Ad Hoc Technical Expert Group on Synthetic Biology”

Thank you for the opportunity to comment on the updated report and synthesis of views related to synthetic biology and on the report of the meeting of the AHTEG on Synthetic Biology.

Biofuelwatch’s focus has been on the wider impacts of large-scale industrial bioenergy and of the policies promoting bioenergy. This includes the application and development of synthetic biology to genetically engineer microorganisms for use in biofuels and/or bioplastics production. Our research shows that several synthetic biology companies which have attracted public sector grants and private investment at least partly for the purpose of developing genetically modified microorganisms for biofuel production have then ended up using them entirely for non-biofuel purposes – e.g. to produce ingredients for anti-ageing skin care products (Solazyme) or nutraceuticals (Amyris). Given the crucial role of biofuels-related grants and investment in creating synthetic biology applications in other sectors, we have been following the wider industrial use of microorganisms developed through synthetic biology.

Given Biofuelwatch’s remit, we confine our comments primarily to the industrial use of microorganisms that have been engineered through synthetic biology methods in order to produce (or help produce) biofuels

as well as other products (e.g. synthetic vanillin, Artemisinin, synthetic sweeteners, ingredients for cosmetic products).

To our knowledge, all existing uses of GMO microorganisms for industrial production are classified as 'contained uses'. Yet, as we discuss below, the risks of unintentional release from industrial production facilities are very high ; they are much higher than they would be from 'contained use' in research laboratories. The one exception we are aware of is the use of genetically modified algae grown in open pond systems, which cannot be classified as contained as it clearly constitutes environmental release.

Comments on the updated report and synthesis of views:

Overall, this report summarises the different points made in different submissions, including our own, very well. However, amongst the various concerns expressed in different submissions, one that we believe is not adequately reflected in this report is about the dangers of not carrying out stringent risk assessments in relation to synthetic biology applications that are classed as being for 'contained use'.

Chapter V of the report does mention the risk of

“accidental exposure to organisms or components of synthetic biology which were intended for contained use causing adverse effects to humans and other

species, including risks associated with bioterrorism”.

However, we are concerned to see the following statement in Chapter VII (“Degree to which the existing arrangements constitute a comprehensive framework in order to address the impacts of synthetic biology, in particular threats of significant reduction or loss of biodiversity”):

55(a) “ Many of the current synthetic biology applications are destined for contained use and are somewhat removed from having a direct impact on the environment and biodiversity. The discussion on the impacts of synthetic biology would benefit from a focus on the potential impact of organisms that are being developed for intentional introduction into the environment and which are capable of replicating or reproducing.”

We had highlighted in our Submission of Information that we believe that synthetic biology applications which involve the use of microorganisms, including microalgae, simply cannot be reliably contained. Several other submissions also emphasised serious problems with the so-called ‘contained use’ of organisms resulting from synthetic biology. For example, the joint submission by the Federation of German Scientists, EcoNexus and Ecoropa states:

“Given the quantity and often new qualities and makeup of organisms, compounds and products resulting from synthetic biology, rigorous risk

assessment encompassing all aspects (see section I above) should be performed for all applications, irrespective of whether intended for contained use or not. It should always be recalled that one escape could potentially be catastrophic and irreversible, even if the likelihood of it occurring is extremely low.”

We therefore hope that the report can be amended to reflect or at least report on the views expressed by several organisations that “contained use” of organisms, compounds and products developed through synthetic biology cannot be guaranteed and that those must not be exempted from rigorous risk assessment and from application of the precautionary approach.

Comments on the AHTEG Report:

General comments on the AHTEG:

We welcome the AHTEG discussions on synthetic biology. We believe that the working definition, set out in paragraph 24, is a useful definition, one that is broad enough to encompass the many different techniques and forms of synthetic biology.

However, we were concerned to read in paragraph 66 (b) that the AHTEG concludes “*that living organisms developed through current and near future applications of synthetic biology are similar to LMOs as defined in the Cartagena Protocol*”. We believe that such organisms clearly are LMOs as

defined in the Protocol – not just ‘similar’ to them. In fact, this statement appears to contradict paragraph 38 of the report, which says: “*living organisms of synthetic biology would fall under the scope of the Cartagena Protocol and the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress.*”

Comments related to the use of microorganisms developed through synthetic biology for industrial purposes:

Many of the impacts and risks highlighted in this AHTEG report related closely (albeit not exclusively) to industrial uses of microorganisms developed through synthetic biology which national/regional regulations class as ‘contained use’. Examples involving existing uses of synthetic biology include:

- Yeasts and bacteria used inside cellulosic ethanol refineries for the fermentation of lignocellulosic biomass or;
- Bacteria, including cyanobacteria used to convert CO₂-rich flue gases, e.g. from steel mills, to biofuels;
- Bacteria and micro-fungi cultivated in industrial plants for the production of enzymes used in cellulosic biofuel refineries;
- Microalgae grown in photo-bioreactors;
- Industrial cultivation of yeast for the production of farnesene, used to produce synthetic artemisinin, cosmetic products and lubricants for oil drilling;
- Industrial cultivation of yeast for the production

of synthetic vanillin, synthetic sweeteners and likely synthetic saffron (announced by Evolva to commence in 2016).

Many of those applications have significant ***indirect impacts on biodiversity as well as indigenous peoples and local communities*** (or the potential for such impacts should production be expanded). Impacts include adverse effects on small farmers whose income depends on the Artemisia plant or those dependent on vanilla orchids – with the potential for adverse biodiversity impacts if such sustainable forms of agriculture are destroyed. And cellulosic biofuel production, if it was to ever become commercially viable, could create an effectively unlimited new demand for wood and grasses, and thus for land, likely to result in further ecosystem destruction and forest degradation.

Effective containment of microorganisms derived from synthetic biology inside an industrial facility ***cannot be guaranteed***. In the – inevitable – case of unintentional release, all of the risks listed in the AHTEG report apply. The risk of unintentional release from industrial facilities is significantly higher than that from research laboratories: For example, when photo-bioreactors are used to grow genetically modified microalgae, nothing but a simple layer of plastic separates those organisms from the outside environment. Furthermore, these photo-bioreactors have to be regularly rinsed and cleaned, another process which involves risk of unintentional release. Engineered microorganisms and their products that are used inside biorefineries are

being transported long-distances, often across continents, from the laboratories and pilot plants where they have been developed. And refineries tend to be staffed primarily by engineers and other operating staff with no background in microbiology or basic biosafety issues. The inherent vulnerability of different containment strategies and the importance of considering 'social aspects' (i.e. the background of those handling genetically engineered microorganisms in different environments) have been analysed in detail in the CBD Secretariat's Technical Report "Potential Impacts of Synthetic Biology on Biological Diversity".

We were disappointed to see that "some members of the AHTEG noted that risk assessment practices currently in place to evaluate LMOs are sufficient and appropriate to evaluate organisms of synthetic biology" (para 58) and that "*The views of the members of the AHTEG diverged with regard to whether or not current methodologies to address the environmental impacts of the components and products of synthetic biology are adequate or even needed.*"

Firstly, it seems clear to us that existing risk assessment practices, which rely on examining whether host organisms or introduced genes are known to be associated with pathogenicity or other adverse impacts are entirely inadequate in this context. Microorganisms used in industrial settings may have their metabolism substantially re-engineered so as to ferment combinations of sugars that no naturally occurring microorganisms can ferment, as well as being engineered to survive under conditions such as highly

toxic concentrations of ethanol. Or they may have been engineered to produce enzymes which can effectively break down the cell wall structures of plants under conditions very different from those where this would normally be possible (i.e. confined to the digestive systems of ruminants and termites). Since those traits have not been found in any non-modified living organisms, the idea that risk assessments based on assessing the traits of non-modified host-organisms and organisms from which genes may have been transferred (if they haven't been synthetically engineered in the first place) appears nonsensical to us. The inevitable unintended mutations and other impacts on the genome that such major disruptions are virtually guaranteed to produce, are ignored in existing risk assessments. Among other impacts, many microorganisms are well known to be capable of horizontal gene transfer. Potential consequences arising from horizontal gene transfer from microorganisms derived from synthetic biology are not currently not even assessed.

Secondly, existing country/regional regulations applying to so-called 'contained-use' are so weak as to be virtually meaningless. Microorganisms derived from synthetic biology are routinely being classified as having low or negligible risk ("Class 1" in the EU), with minimum requirements for their containment.

For example, in the UK (<http://www.hse.gov.uk/pubns/priced/l29.pdf>) , risk assessment for any genetically modified microorganisms are carried out by the 'user' – which could be a biofuel

company or another industrial user of such microbes or their products. The organisms are assessed solely by an in-house committee or 'competent individual'. The only contact with a government authority may be a notification of 'contained use' of a modified microorganism, which the applicant has categorised as falling within 'Class 1', followed by a permit. There is no requirement for any inspections, not even for annual reports. Nor is there any requirement to monitor the effectiveness of containment measures. Staff training relevant to the containment of such microorganisms does not need to be recorded. There is no legal requirement to physically contain such an organism at all: Under UK regulations, a single genetic modification classified as 'biological containment' will be sufficient to comply with 'containment' rules for organisms classified as "Class 1" LMOs. Meanwhile, the CBD's Technical Report discussed in detail why such biological containment strategies are far from fail-proof. Even in the absence of biological containment measures, no measures to prevent such microorganisms from entering waste effluents have to be taken.

Clearly, the risks highlighted in the AHTEG report cannot be prevented with such weak regulatory procedures. We believe addressing risks of industrial use of microorganisms derived from synthetic biology, which is, very questionably, defined as 'contained use', must be one of the urgent priorities of the CBD's future work on synthetic biology. All such uses must be subject to stringent and comprehensive risk assessments and the application of the precautionary approach. This is particularly urgent given the pace and

scale of developments, and given that currently national level regulations provide a gaping loophole by classifying so many uses as "contained" when they clearly should not be – and by requiring no effective risk assessments, nor enforcement of stringent biosafety measures for many such uses.

Comments related to Item 4 “Conclusions and Ways Forward”, Paragraph 66:

We strongly agree with the reaffirmation of the precautionary approach in relation to synthetic biology, set out in decision XII/24 .

We also very much agree with sub-paragraphs (a) (working definition), (c) (monitoring and assessment of the state of knowledge within the field of synthetic biology), and (k) (involvement of indigenous peoples and local communities).

In sub-paragraph (b) we hope that the wording can be amended to “living organisms developed through current and near future applications of synthetic biology are LMO’s as defined in the Cartagena Protocol”.

In relation to sub-paragraph (e), we believe that ‘coordinate and establish synergies’ should be replaced with “exchange information”. Not all of those organisations have a mandate and approach to synthetic biology that reflects the mandate of the Convention on Biological Diversity. We believe that the CBD must take a leading role in relation to synthetic biology because no other body has the same remit and

expertise in relation to protecting biodiversity and indigenous peoples and local communities livelihoods that rely on biodiversity.

We further believe that recommendations should emphasise the need for effectively applying the precautionary approach to synthetic biology, which must involve stringent and holistic risk assessments of all organisms, components and products derived on it, including those whose use would currently be classified as ‘contained use’. In this context, we would point to COP 10 decision X/37 on Biofuels and Biodiversity, paragraph 16, which

“Urges Parties and other Governments to apply the precautionary approach in accordance with the Preamble to the Convention, and the Cartagena Protocol, to the introduction and use of living modified organisms for the production of biofuels as well as to the field release of synthetic life, cell, or genome into the environment, acknowledging the entitlement of Parties, in accordance with domestic legislation, to suspend the release of synthetic life, cell, or genome into the environment.”

Note that this wording applies to both the use of such organisms inside biorefineries (‘for the production of biofuels’) as well as to field release. Clearly, this decision closely relates to synthetic biology and it explicitly extends the precautionary approach to important industrial uses of organisms derived from it (which supports our view that it should be extended to

industrial uses in general).