Intro: I think the Protocol requires and introductory section that says what it is (and is not).

Para 2: I think you jump into specific examples too rapidly. I would say

> "The new biotechnologies include, among others, symbiotic control, genetic improvements to the Sterile Insect Technique, various modifications using the intracellular bacterium *Wolbachia*, and attempts to modify the genome of a pest insect so that it becomes less able to transmit disease.
>
> 'Symbiotic control', also known as 'paratransgenesis', refers to any of various strategies in which microbes associated with a disease vector insect are modified to produce anti-pathogen molecules, thereby reducing the tendency of the insect to transmit disease. This approach can be applied to human, animal and plant diseases. Major targets for this strategy include Chagas' disease (humans), trypanosomiasis (livestock and humans) and Pierce's disease (grapes).
>
> The Sterile Insect Technique is an environmentally friendly method of pest control that relies on the mass-rearing, sterilisation –currently by gamma radiation – of pest insects. Successes include the eradication of the New World screwworm, a lethal parasite of human and animal flesh, from North and Central America. Various biotechnological improvements have been proposed or developed, for example to remove the need for gamma radiation by genetic methods. Such methods are being develop for various fruit flies, mosquitoes and moths; engineered strains of pink bollworm, a moth pest of cotton, have advanced to open field trials.
>
> *Wolbachia* is an intracellular bacterium that has several diverse potential applications in biotechnological approaches to reducing disease transmission and crop damage by insects, including sterilisation, life-shortening, and helping to drive beneficial genes through pest populations. See the *Wolbachia* information website at http://www.wolbachia.sols.uq.edu.au/ for more information.
>
> Methods have also been devised to prevent insects transmitting diseases by directly modifying their genomes to make them resistant to the relevant pathogen. This work is most advanced in mosquitoes, aiming to prevent them transmitting diseases such as malaria and dengue. Methods are also being developed to enable these genes to be spread into large wild populations, thereby protecting large areas from these diseases. Other new applications of biotechnology are likely soon to be developed for other biological control purposes."

Page 1 para 6: Good. However the full (i.e. correct) name of 'the Gates Foundation" is something like "The Bill and Melinda Gates Foundation"

Page 2 para 1: 'potential exposure <u>of</u> vulnerable nontarget organism' rather than '<u>to</u>'?

Page 2 para 4 and following:
I am very concerned about the emphasis given to EIA as the recommended assessment route. The EIA/EIS is the most heavyweight – and expensive – version of impact analysis, costing millions of dollars and taking at least 18 months, often much longer. At least in the US, none of the early biotech crops underwent an EIS, though I believe a couple of the most controversial recent ones have done so. Though this level of analysis may be appropriate in some instances, to insist on it in all or most cases, as the Protocol currently appears to do, will kill this technology at birth. Few of the parties potentially interested in or capable of doing this work have the resources to do an EIA/EIS. Major established industrial players in the GM crop field may now find it the process beneficial as the requirement puts up a substantial barrier to entry for potential new players; this is not a reason to advocate the system but rather the opposite.

In the US, as I understand it, the regulatory standard would be to do and Environmental Assessment (EA), which is generally a much cheaper, quicker and lighter-touch assessment because it focuses on the key points, rather than trying to be completely comprehensive. If this EA leads to a Finding Of No Significant Impact (FONSI), then the permit is awarded, if not it may go to an EIS. The current US EIS for autocidal methods for pink bollworm and fruit flies is not being conducted as part of a regulatory process, and transgenic pink bollworm have gone through to open field trials with EAs only. [As I understand it, the EIS is being done because (i) USDA-APHIS gave a commitment some years ago to do one and (ii) there is or maybe a requirement under NEPA for APHIS to do one; this requirement relates only to US government agencies, who must consider the potential impact of each of their programs on the environment. No such NEPA requirement would exist for a university, charity or private company wishing to use or develop such technology]

Page 4 EIA format
It is incorrect to state or imply that the IAEA are either a regulatory agency or maintainers of an existing international agreement in this area., or indeed have any privileged position whatsoever in this respect. I think that the same applies to WHO, but am not so certain. Formally, the IAEA (FAO/IAEA joint program) are just a bunch of scientists with an interest in SIT. They have certainly commented on containment and various other issues, but their opinions hold no greater legal authority than anyone else's, i.e. none at all!