**Email from Paul De Barro – his thoughts on contrasting issues of release of gene drive organisms and biocontrol agents.**

The considerable difference between the release of the GMO and a biocontrol agent is how the release process is regulated. In the context of GMOs the release process is a regulated process whereas in the case of the releases of a biocontrol agent there is no such regulation. With a biocontrol agent once the risk is assessed and deemed to be low, the regulators will most likely make the decision to allow a release to occur. That decision is made at the level of the country - not part of it. The rational here is that the biocontrol agent is designed to spread and the process of release that the researcher develops is designed to do two things

1. maximise chance of establishment
2. maximise the opportunity for rapid spread of the agent

How this is done depends on 3 factors (usually)

1. the biology and behaviour of the agent - how quickly it reproduces (builds up numbers) and how quickly it spreads.
2. the amount of money the researcher has to fund the release
3. the distribution of the target
4. seasonal variation across the target distribution range

The release process then usually falls into one of two modes. The first is you establish nursery sites where the first releases are made and then you use these to seed subsequent releases. This is often used in the case where producing sufficient individuals in cultures is difficult or the agent has a long lifecycle. The second is you do multiple releases across the range of the target so that you have multiple populations seeded from which natural spread then occurs. You may follow this up with subsequent releases to fill in the gaps.

So, once the regulator has approved the release you are pretty much free to releases it where ever you want and in whatever way you decide is the most effective. There is also no formal process of post-release evaluation and monitoring. In fact for many agents there is very little after the first year of releases as funding usually ceases once the release period is over. This is considered a flaw as often useful data about impact etc is not gathered, but that is not really relevant here and it is certainly of no interest to the regulator whose role ceases once permission to release is granted.

So there is no formal process to assess level of post-release monitoring and so there are no time frames or distance (area) over which the release must be monitored. By way of example I have attached a paper relating to the release of the whitefly parasitoid, Eretmocerus hayati. As you will see we were given permission to release in Sept 2004 and moved straight into the field releases from Oct 2004 across the state of Queensland. How we undertook the releases, where we carried out the releases and how we undertook post-release monitoring was entirely up to us. There was no requirement to report back anything to the regulator.

So, I think here there is a substantial departure as to the usefulness of biocontrol releases as a guide to inform the practice of a gene drive mosquito releases. It is highly unlikely that the regulator responsible for the release of a gm mosquito is going to say 'off you go, releases it where ever you want, we don't care as it is no longer our responsibility'. In this case you are going to need to comply with a whole set of release conditions whereas for a biocontrol agent there is no such process.

I have attached a paper in relation to current release of a new strain of rabbit calicivirus into Australia. As you will see the plan is for a coordinated release across 600 to 1000 sites across Australia. This is about as regulated as it gets for a biocontrol agent. In effect the releases are to be coordinated across the country through the various States to ensure rapid coverage of as much of the rabbit population as possible. Section 5 covers the release program. As you will see in the report covers who is authorised and again this is very much the exception and is purely there to ensure efficient distribution and maximising likelihood of an effective outome. It has nothing to do with biosafety etc.