**Advice: Application process to Environmental Protection Authority (EPA) in NZ.**

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**The HSNO Act 1996 dictates that substances containing a new organism or genetically modified organism, not present in NZ prior to July 1998, must be approved for importation by the EPA. This will include many new vaccines employing genetic engineering of live, attenuated organisms.**

**The process:** <https://www.epa.govt.nz/industry-areas/new-organisms/applying-for-approval/what-are-the-steps-for-processing-an-application/>

There is a ***pre application process*** which will be of unspecified duration (can be reasonably quick or very slow), during which time the EPA scientists should be in direct communication with the Sponsor’s scientists, with many rounds of questions and answers to be expected. The object of this process is to allow the EPA to assist the sponsor to craft their formal application in such a way that it has the best chance of success. This should be viewed as a constructive process between scientists and one that requires open and full disclosure of information regarding the new organism. This process should be initiated as soon as there is serious thought being given to involving NZ in a future trial. It may not always be followed by a formal application.

Once the pre-application process is complete **a** ***formal application*** may be lodged and statutory timelines come into play. A decision will be made by EPA after receipt of the formal application as to the pathway that will be followed, based on a defined set of criteria. For GM medicines and vaccines, a non-notified pathway is most likely to apply and possibly the HSNO rapid application process will apply. In this case the statutory time frame for the decision to be made is within 10 days of formal receipt of the application (ie confirmation of complete application and receipt of payment), followed by another 10 days for both the applicant and Public to be notified. (see overleaf for the steps involved in the HSNO rapid application process). Other pathways will take longer.

**Keys to success in the pre-application phase**

* Early engagement – scientist to scientist (not Regulatory or Clinical Research Dept or CRO)
* Begin with a phone call or email outlining that consideration is being given to a full application
* Recognition by sponsor that confidentiality is paramount for the EPA
* There will be multiple rounds of questions and answers
* Each application is likely to be different, and treated as such
* All relevant matters should be answered as fully and openly as possible
* Be prepared to share information given and received in other jurisdictions
* The risk assessment process begins during this pre-application phase and will inform the final risk assessment given to the formal application, upon which a decision will be made.

**Remember**

* The EPA scientists are there to help … don’t be evasive
* Full and open disclosure is essential. Confidentiality will be maintained.
* The EPA scientists like these applications, as they often involve cutting edge technology
* The purpose of this pre-application stage is to give the formal application the best chance of success
* Expect that some lengthy international phone calls are likely to be necessary
* **In the face of uncertainty, the HSNO Act requires the EPA to take a precautionary approach**

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