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January 21, 2010

Dear Dr. Tucker,

The American Biological Safety Association (ABSA) is an international group of biological safety professionals that is recognized as one of the world's foremost resources on biological safety practices.

We have reviewed the Screening Framework Guidance for Synthetic Double Stranded DNA Providers which was published in the November 27, 2010 Federal Register. Please consider the comments which follow regarding this document.

The guidance document is a commendable step in achieving enhanced biosecurity at the molecular level before genetic material of concern is delivered to parties who could misuse it. Because it is a voluntary guidance document, there needs to be a careful balance of risk and of being overly restrictive in its provisions if it is to be used by the intended industries. Consideration should be given for the use of a 1 kb screening threshold verses a 200 bp screening threshold. Use of the 200 bp screening threshold results in the translation of a coding region of only 67 amino acids. This sequence is large enough for a regulatory signal, but it is not large enough for a toxin or pathogenic gene. If the objective of this guidance document is to prevent the generation of fully pathogenic pathogens or the generation of genes encoding virulence factors, then the use of the larger screening threshold would better accomplish these objectives with less strict guidance.

Software to be used in the proposed screening of DNA sequences poses some considerations. Utilization of the same software by all parties engaged in this task would better assure that data generated by all parties is consistent. Consideration should be given to the universal provision of this software free of charge to all parties. This step would facilitate its use by the intended parties.

Consideration should be given for the use of software from the National Center for Biotechnology which is accessible from its internet site. Proper training in the use of the software would also be important if its use is to yield useful data. Without careful selection of parameters, its use will result in either “no hits” or “a great number of hits” from the screened DNA sequence. Clear guidance must also be provided to software users regarding results that can be interpreted as being significant, and results that cannot be interpreted as being significant.

Steps such as these would help facilitate the extra preparations that companies would take to voluntarily engage in the non-regulatory tasks detailed in the document.

Consideration should also be given to providing these companies with a single point of contact within the government. Interpretation of the DNA screening data requires a technical background that staff at some of the involved agencies may not have. A single point of contact would also facilitate the consistent collection and evaluation of sequenced data, as well as facilitate its sharing with all concerned agencies.

We appreciate this opportunity to have provided this input.

Ben Fontes, MPH, CBSP

A handwritten signature in black ink, appearing to read "Ben Fontes". The signature is fluid and cursive, with a large initial "B" and "F".

President,  
American Biological Safety Association (ABSA)