ARE THE FSA "MAKING IT UP" AS THEY GO ALONG?

Until today there were two options following the submission of a Novel Food application: Validated or Unvalidated. It now appears as though there is a third: Unvalidated, but heading in the right direction.

We say this because the FSA website has been updated with the following statement:

> *A list of products linked to validated applications will be published on the FSA's website in April and regularly updated.*
>
> *The FSA will also publish a list of products associated with applications which have not yet fully met the legal requirements to be validated but have set out sufficiently robust plans to prove they are fully committed to delivering the remaining information required. This will include evidence of plans to complete the risk assessment process, with a clear deadline for submission of the outstanding information.*

It is unclear whether this is a way of saying that there can be no Validation without the submission of toxicology data, or otherwise. If it does mean "no tox = no Validation", then this is in contradiction to what the FSA told us in July of last year when we interviewed Paul Tossell (Head of Novel Foods) and Frances Hill (head of the Novel Foods science team) for three hours and directed these specific questions to them. The video of the interview continues to be available for free via this link.

Those who follow our thoughts on the UK Novel Food process and the FSA's approach to it will be fully aware that we are significant opponents of the FSA's "New to Market" policy and that, in our view, for the reasons that we have outlined previously it will not sustain a legal challenge to its validity (our long-held analysis can be found here).

We would suggest that the absurdity of the unintended consequences of this naive policy are perhaps drawn into closer focus when one overlays the "new" quasi-validated category above.

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As a result of the combination of the two policies you can now have the following situation:

(a) Applicant A, who was on the market on 13th February 2020, submits a Novel Food application unsupported by any toxicology. They are granted the new "unvalidated, but heading in the right direction" category and are "permitted" by the FSA to continue selling to the public – despite such conduct being unlawful; and,

(b) Applicant B, who was not on the market on 13th February 2020, submits a Novel Food application supported by full toxicology data through their own OECD-408 study. They are "fully Validated" but are not "permitted" by the FSA to continue selling to the public.

One is caused to question how the public are more protected in respect of Applicant A's products, or more exposed to danger from Applicant B's products. In reality, the opposite is the case in that the public are more protected in respect of a product which has undergone toxicology testing and in respect of which the results are favourable.

We appreciate that Validation is not the same as Authorisation and that the risk assessment phase has not taken place, but on any version there is more data supporting a safe product for Applicant B than there is for Applicant A. Despite this, the policy of the regulator in charge of public protection favours the product which is less safe than that which is likely to be more safe.

This does not seem to us to be a credible position for a regulator to take and, as we have always said, the defining criteria for whether a product should be permitted to remain on the market should be whether it has been Validated.

Remember what we always say: ***Be Careful Who You Listen To.***

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