

NOVAQ10[®]

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Datum: 24. Juni 2016

LabNr. 2725: Are micelles contained in NovaSol solubilisates engineered nano material (ENM?)

AquaNova since 1996 applies a patented procedure to encapsulate various bioactive compounds in micelles of polysorbates. Lipophilic substances are thus rendered water miscible and better bioavailable, hydrophilic and/or reactive substances are rendered more stable and get improved delivery at the site of action.

Those micelles are of nano scale, having diameters of 30 – 100 nm. They are forming a transparent sol in water.

Task: a compilation of relevant scientific and legal aspects of qualification of these micelles, with specific consideration of engineered nano materials (ENM) and late legal developments, such as novel of novel food regulation, regulation (EU) 2015 2283 on novel food. Hereafter, we will name this regulation NNFR.

This NNFR, in force since December 2015, is generally valid from January 1st, 2018.

Position

1.) What is a nano material, what an ENM?

The latest Definition is found in NNFR, Art 3. where we can read

„f) „engineered Nanomaterial“ a material produced on purpose, which in one or more dimensions has a size of 100 nm or less, or the inner structure or surface of which consists of functional parts of which many have in one or more dimensions a size of 100 nm or less, including structures, agglomerates and aggregates which might exceed 100 nm but retain the properties conferred by their nanoscale origin.“

The definition of nano structures, i.e. that they have one or more dimensions in the range of 1 – 100 nm (only < 1nm; otherwise, in the a.m. definition, all molecules would be included), has to be carefully discerned from the definition of artificially produced, engineered nanomaterials.





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The latter are produced on purpose with technical processes from (earlier: only inorganic) material (earlier: that would per se not exist in nano structures). Nowadays, also organic materials are included. Importantly, „processing“ or „engineering“ are not defined – which would be important in the context of materials whose intrinsic properties lead to formation of nanostructures, whether engineering or not. It is not clear, whether „engineering“ only means mechanically forced formation of nanoscale surface structures from inorganic minerals, or the chemical synthesis of nanoscale molecules (e.g. fullerenes; how about proteins??) or whether even the formation of micelles is covered.

Nano structures are widespread in nature, e.g. surfaces of certain plants („lotus effect“ was name giving once upon a time), or emulsions in egg yolk or milk. Physical and chemical properties of the building substances naturally lead to nano structures. Consensus has been achieved that these are not ENM.

Borderline cases: in the context of food, silicon dioxide as additive is now discussed controversially for nano structures – has this been the case, and therefore taken into account, during the approval process? - If production has been changed as to now lead to nano structures, a new approval is necessary. Titanium dioxide, for example is indeed produced differently as to yield transparent yet UV protecting ENM. Nano silver more and more comes into discussion for its antibacterial activity, useful for fabrics, packaging material and theoretically for food itself. This of course would be a case for the biocidal products approval scheme.

Definitely engineered is mayonnaise – containing nanoscale micelles. EFSA has written down, in its approach on risk assessment for ENM¹ :

"Natural" nanoscale materials (e.g. micelles) will be considered if they have been deliberately used e.g. to encapsulate bioactive compounds or further engineered to retain their nanoscale properties. "Natural" nanoscale components present as emulsions (e.g. in homogenized milk, mayonnaise, etc.) will not be considered."

What does this mean? If intrinsic properties of materials do lead, in an engineering process, to nano structures, e.g. micelles, those do not need risk assessment. If, on the other hand, *expressis verbis* named micelles are enclosing bioactive compounds, then risk assessment would be necessary.

EFSA opinions are by nature scientific opinions, well substantiated, but not legally binding. They are meant to support political decision, but politicians also need not adhere

It is obvious, and reasonable, that emulsions / nano micelles that do form due to intrinsic properties of substances are not subject to Risk assessment as ENM. It can however not be confirmed that a case of micelles encapsulating bioactive compounds not being ENM would stand in court.

In the light of NNFR, the mayonnaise case is obsolete anyhow.

1 SCIENTIFIC OPINION The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety 1 Scientific Opinion of the Scientific Committee (Question No EFSA-Q-2007-124a) Adopted on 10 February 2009, S. 7



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2.) Are ENM subject to approval?

ENM are subject to approval procedures, actually only as food additives, in the future (from Jan. 2018) under NNFR.

Polysorbates are approved as food additives. During the approval process, micelle formation and eventual specific properties due to that have been taken into account appropriately. Approval of polysorbates as food additives took place long before the reference date in NNFR.

3.) What is a novel food?

Normally, this would be defined in NNFR. The relevant paragraphs are not easily understandable. Commonly, legal experts consider the law failed on the aims of clarification and simplification². Therefore may the undersigner pose the *caveat*, that interpretation of this law is not necessarily standing in court.

Art. 3 of NNFR prescribes: „ novel food are those, which have not been consumed in significant amounts before May 15, 1997 AND are falling in one or more of the following categories:

vii) food, for the production of which a process has been used not in common use before May 15, 1997, which confers significant changes in composition or structure of a food, which have influence on its nutritive value, its metabolism, or its contents of undesirable substances“

This means that, even if the manufacturing process of Aquanova would be considered uncommon, the solubilisates would be novel only if significant changes in composition, structure or metabolism of the food would come along with that.

But now, a new ident has been included:

„viii) food, that consists of engineered nano materials as defined in ident f of this article“

The definition mentioned is reproduced further above. Only if consumed in significant amounts before May 15, 1997, ENM escape the law. The „significant amount“ is not defined, jurisdiction expectedly does interpret this criterion widely different.

Also, material that is not engineered in the meaning of the definition is not covered. The undersigner clearly allocates the solubilisates of AquaNova not being engineered in the meaning of the definition, but it can again not be guaranteed that this interpretation stands up in court.

This ident viii supposedly leads a manifold of usually early informed activists to frequent publications that ENM would be principally subject to approval. But: NNFR is valid from January 2018 only.

By the way: the scope of NNFR in art. 2 does not include „food that is used as additives, aromas or enzymes“. Whatever „food“ in this context does mean, at least it means not only single substances.

² <https://meyerlegal.wordpress.com/2016/01/25/neue-novelfood-verordnung-20152283-chance-vertan-ein-kommentar/>



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So, if polysorbates are used as additive in a food additive preparation, they are not within the scope of NNFR.

The solubilisates of AquaNova are produced using only common procedures such as stirring, heating and cooling, being in use long before the decision date of NNFR. Neither structure nor composition as well of polysorbates as well as of bioactive compounds enclosed are changed in comparison to their natural properties. Solubilisates consisting of micelles do emerge solely by exploitation of their intrinsic properties, especially critical micelle formation concentration, in the production process.

Therefore, the solubilisates produced by AquaNova are not to be considered being NEM nor novel food and thus do not require approval.

Because of uncertainties in the legal basis, a fall-back question should be addressed: what if (someone would decide AquaNova solubilisates are ENM)?

Scientific consensus is, that nano structure does not pose a risk in itself. Therefore, for the time being, there is no central approval regime for ENM.

The regulation on information for the consumer about food (EU) 1169/2011 just poses a declaration obligation for ENM (based now on the same definition as in NNFR).

Approval regimes are foreseen only in specific legislation such as food additives regulation, biocidal products regulation (both without specific respect to nano structures, but risk oriented) and now NNFR. These approvals are necessary only if a material is within the scope of the resp. legislation. In the course of general risk assessment in these regimes, also nanoscale driven properties would be captured.

According to the knowledge of EU commission and national authorities, for the time being there is no application of ENM in food.

(Dr. Walter Gekeler.)