



Overview of Regulatory Perspectives: REACH, Plant Protection and Animal by-Products

Brussels, 6th June 2019 Mariano ALESSIO VERNI'

CONTENTS

- Reach Regulation (1907/2006): when the «organic» is involved
- EC Regulation 1107/2009: biostimulants and organic PPPs
- Animal-by-products (EC Regs 1069/09 and 142/2011): critical issues



REACH

- The EC Reg. 1907/2006 also affects organic based fertilisers
- When REACH registration is not required:
- 1) Waste
- 2) EU Recovered substances
- 3) Substances which occur in nature
- 4) Substances obtained from natural sources
- 5) Polymers
- 6) Compost, biogas

... BUT

- The substance that results from the recovery process must be the same as the substance that has been registered
- Substance that occurs in nature: if it is not chemically modified AND it is not dangerous (CLP)
- 3) Substances obtained from natural sources: it applies to vegetable fats, vegetable oils and vegetable waxes but does not cover essential oils
- Polymers: monomers have already been registered by the supplier or another actor up the supply chain
- 5) In case a substance has been registered, the dossier (CSR) must include the "use" as fertiliser
- 6) Compost and <u>digestate</u>: EU Council has approved (last 17th May) the inclusion of digestate in the Annex V of Reach

EXAMPLE (1)

- Seaweeds are substances occuring in nature and are exempted only if they are processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water
- Not by chance, the Ascophyllum nodosum, ext. and the Enzymatic hydrolysis products of Sargassum hemiphyllum, ext. have been registered under Reach

EXAMPLE (2)

- Leonardite is exempted from the registration requirements
- If we use potassium hydroxide, Leonardite changes its chemical composition and it becomes dangerous
- Not by chance, the "Humic acids, potassium salts" has been registered under REACH
- NOTE: Many substances that might fall into the 'substances which occur in nature' category have insufficient information available on the market to conclude that they are not dangerous
- We must gather information on these substances in order to determine their potential hazards

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1107/2009 Amendments

- Article 2 (Scope) This Regulation shall apply to products ...
 consisting of or containing active substances .. and
 intended for one of the following uses: ...(b) influencing the
 life processes of plants, such as substances influencing
 their growth, other than as a nutrient or a plant
 biostimulant;
- Consequently, a new definition (#34) has been included in article 3:"plant biostimulant" means a product stimulating plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere: (a) nutrient use efficiency; (b) tolerance to abiotic stress; (c) quality traits; (d) availability of confined nutrients in soil or rhizosphere

Organic & PPP overlaps

- The Organic Biostimulants could be PPP too
- Hydrolysed proteins are an active substance (attractant), authorised in CY, EL, ES, FR, IT, PT
- Sea Algae extract is a plant growth regulator, authorised in B
- Trichoderma atroviride is a fungicide, authorised in AT, BE, CY, DE, EL, ES, FR, IT, LU, NL, PL, PT

Dual use

- ONLY in case an active substance falls under the definition of plant biostimulant, the PPP regulation shall continue to apply up to the end of the authorisation
- Hydrolysed proteins or a Sea weed extract can be labelled as organic fertiliser to provide nutrients
- Organo-mineral fertilisers can contain Copper, Iron, Sulphur, etc. without claiming defense actions
- Only Phosphonates shall not be <u>intentionally</u> added

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Acronyms (Regs 1069/09-142/2011)

- animal by-products = ABP
- derived products = DP
- organic fertiliser and soil improver = OFSI
- End Point = EP
- no longer pose any significant risk to public or animal health=EPR
- processed animal protein = PAP
- hydrolysed proteins = HYDP
- meat-and-bone meal = MBM
- processing plant = PROCP
- Fertilisers manufacturing plant = UFERT
- Processed Manure = MANP

ABP Reg. Amendments

- The art. 5 (2) did not include OFSI among the DP for which an EP could be established
- For this reason, art. 32 (concerning OFSI)
 has been included within the DP which could
 EPR
- Consequently an EP may be determined, beyond which the OFSI are no longer subject to the requirements of the ABP regulations

ABP Reg. Amendments

- Point 4 has been included in art. 5
- Within December 2019 the Commission shall initiate an assessment of the DP widely used as OFSI
- The assessment shall cover <u>at least</u>: MBM, HYDP, PAP, MANP, DP from blood, hoofs, horns, etc.
- Where the assessment concludes that those DP no longer pose any significant risk to public or animal health, the Commission shall determine an EP in the manufacturing chain
- Finally, art. 51a (Exercise of the delegation) has been included: under some rules, the Commission can adopt delegated acts on art. 5(2)

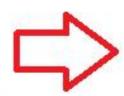
ABP in the new Reg.

- The Regulation does not apply to: ABP or DP which are subject to the requirements of Regulation (EC) No 1069/2009 when made available on the market
- The conformity assessment procedures
 (Annex IV) provide that where the EU fertilising product contains or consists of DP, the documents pursuant to the ABP Reg.
- Moreover, it is required the evidence that the DP have EDR in the manufacturing chain

Before or always?

- CMC 10 (DP under 1069/09 Reg.) definition:
- An EU fertilising product may contain DP having reached the EP in the manufacturing chain ...
- ... and which are listed in the following table and as specified therein: (now the table is empty)
- Does it mean that the DP must arrive to the UFERT already having reached the EP?
- The ABP to which the ABP Reg. does not apply be therefore different from CMC 10?



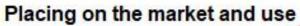




manufacturing chain



Made available on the market











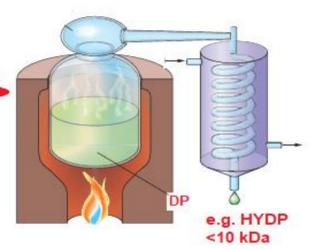










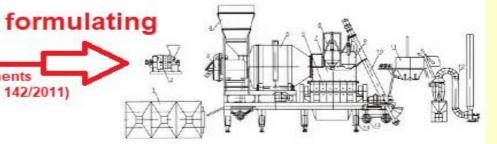












Supporting...

- In the #22 Whereas of the Reg. 1069/09: ... For certain products regulated under other Community legislation, such an end point should be determined at the stage of manufacturing...
- Article 22 (2) of the regulation 142/2011: The placing on the market of the following is not subject to any animal health conditions (EDR?): ... ready-to-sell growing media with a content of less than: (i) 5 % in volume of PAP / MBM; (ii) 50 % in volume of MANUP
- Art. 3(b) (142/11) provides the EP for processed petfood and one of the requirement is: «must be packaged in new packaging»



TAKE-HOME MESSAGE

- You must prove the Reach Registration Exemption
- PPP active substances could be organic fertilisers (under certain rules)
- We must cooperate with the Commission to clarify the EP matter
- The "positive list" can only work if the specific provisions for DP require processing at the UFERT levels
- We prefer a list of processing methods applied for each DP, bringing to an End Point
- ABP derivatives are a renewable source of nutrients: we cannot allow their use to be limited





Thank you for your attention!



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