

‘Microbial plant protection products help improve growing wheat and cereals in a sustainable way in the EU’

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Let me start with a personal touch on this subject. My own experience in research and registration of microorganisms has just passed 40 years. I witnessed the start of biocontrol with a hand full of products and over the years they have extended to hundreds and hundreds. So Research & Development delivered its innovative products but have they reached the EU market? Many products and companies have not made it. That is why I did, after 25 years in the industry a PhD thesis on this very subject with the title “A roadmap to the successful development and commercialization of a microbial plant protection product”. It aims to help academics, start-ups and SMEs be successful. But what is not in the hands of a product developer is the registration process. That is the job of the authorities. Did they adapt? Did they see the new innovative biologicals coming? Did they develop new methods to assess these new products. No, they did not, at least not enough and not in time. Even to date, European Commissioner for Health Dr Stella Kyriakides formally acknowledges that national authorities still do not have the appropriate knowledge or experience to deal with microbial plant protection products.

Since at least 5 years the majority of new active substances submitted in the EU are biologicals!! Every authority knows this. But why have the procedures not been adapted to this trend? One could speculate on the reasons. Is it fear for the unknown? Interests of vested industry and its connections that cause delay? Is it lack of expertise and experts? Lack of resources? Why not repair this in time? Did we not see the negative effects of the chemicals on biodiversity, soil fertility, pollinators, health of farmers, etc. It seems we did, as many groups of chemicals were taken from the market, but new chemicals entered and replaced them. And again we learned about their negative effects. Why not go for more biological and natural solutions? We have seen those developments in other parts of the globe. We cannot easily repair the past, but we have a chance for the near future, the very near future. The alternative products are here and are being developed as we can see in the USA, Brazil and even China. They all have many hundreds of biologicals on the market, however in the EU we are far behind and every day the gap is growing. As an example: our subsidiary in Brazil treats annually about 5 million hectares with biologicals while we do only a few percent thereof in Europe. And we anticipate much stronger growth in Brazil compared to Europe, and our investments reflect this. The products from Brazil could be used in the EU as well and we can approve them quickly. But it needs a dedicated system for those products with experienced scientists in the fields of biology and ecology.

The EU Com has recently adapted the data requirements for applications of microbials. They suggest it will also speed up approvals. But they have not adapted the system, the procedures with its long timelines and have not prioritised the biologicals to achieve the goals of the F2F and Green Deal: a more sustainable agriculture that our society wants and needs.

This Task Force was established about a year ago based on the concern that two microbial PPPs are going to be lost in the renewal process. Two products, one based on a bacterium and one on a fungus, that have their use in arable crops, in cereals like wheat. They have been used for over 15

years as seed treatments, against soil diseases and as foliar treatments for other diseases. They are about the only ones approved for arable crops where we desperately need alternatives to chemicals. Koppert may lose its product completely and with that all our investments of many millions of Euros. Three plant protection products have been developed based on the bacterium. Example applications are cereals including wheat, rye, barley, oats and vegetables including carrot, peas, recently also for foliar applications. Product authorizations have been granted in 15 EU countries. Over time the products have been used on 3.500.000 ha and 1.350.000 L chemical fungicides have been substituted. Biopreparaty has developed a biofungicide based on a fungus. It has been approved since 1995 and is now authorized in 22 Member States and it has been used from 2014 till today on 810,000 hectares, replacing an equivalent of 810,000 litres of chemical fungicides. Applications are conducted in various crops, mainly foliar application in cereals, oilseed rape, vegetables, berry crops and grapevines.

In some markets these products are the only non-chemical solutions available! Chemical fungicides are disappearing from the market and the toolbox of farmers is getting emptier all the time. The products have the potential to increase strongly in coming years! They are the few biological products for arable crops where IPM and biocontrol is urgently needed. And now they are threatened to be taken from the market, just because the wrong questions have to be answered, questions appropriate for synthetic chemicals, but not for living microorganisms. And we cannot answer them hence the potential withdrawal. But they were approved 25 years ago. The Member States that evaluated them recently approved them again. However, EFSA and COM ignored this, so there is a remarkable and fundamental mismatch in the authorization system.

The updated data requirements, will become official by the end of this year. Whether they will improve the process, we will know 5-7 years from now, 5-7 years!! This comes close to 2030 the timeline for the ambitious F2F strategy. But they, EFSA, MSs and COM apparently need to still build and develop their expertise on biologicals and improve and speed up the procedures. The only remedy is a fast track procedure. As Arnold & Porter have demonstrated, this can be done within the framework of and without changing Reg. 1107/2009. Anyone who chooses a longer road plays into the hands of further delay, more research and more time for chemical pesticides to continue their sometimes harmful use. Commissioner Kyriakides recently said **"Today, we are bringing good news to European farmers to help their transition away from the use of chemical pesticides. Biological products can protect their crops with less risk to human health or the environment."** . The Commission's own website states that "they [microbial plant protection products] are also inherently safer than chemicals".

Indeed, microbials are safe and effective. They are already more than 50 years on the global market and never has one product been withdrawn due to harmful effects, anywhere in the world. Our society, our farmers need them now for a sustainable agriculture and for reasons of biodiversity, soil fertility, clean water, food security and food safety.

Why are we so behind in Europe? Why such a long registration procedure 5yrs vs 2 years. Can SME's wait for so long after years of investment? Is that how innovations are treated? Why are our companies moving away to these other markets?

We want to help, as the biocontrol industry, we know our organisms best and have experience in other jurisdictions that can provide solutions. That is why we established this Task Force and drafted the Legal Opinion and the draft Communication which are presented today. We call on the media to verify each and every word I have used, and on that basis to consider challenging the European Commission to put its money where its mouth is. The European Union has shown the

Russian aggressor in Ukraine how unified and determined it can act. Commissioner Kyriakides has declined the effort by industries and EU Member States to halt key elements of Europe's Green Deal and Farm to Fork strategy. This is the season of change, this is the time to prioritise human lives and prosperity over short-lived perceived profitability. This is the moment to finally use Regulation 1107/2009 to make our agriculture more safe and sustainable.
