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OUTLOOKS ON PEST MANAGEMENT

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COVER PHOTOS: Cotton bollworm (*Helicoverpa zea*) (Photo by Scott Bauer) *and Aedes* (*Ochlerotatus*) *sp*. mosquito on human skin both reproduced courtesy of USDA-ARS; Cocoa showing both frosty pod rot (*Moniliophthora roreri*) and witches' broom (*M. perniciosa*) on the same branch (Ecuador) (Photo by Roy Batemen); Unsprayed strip in sugarbeet showing poppies (*Papaver* spp.) (Photo by Alan Dewar)

BIOPESTICIDE SUMMIT – REGULATORY REFORM OF BIOPESTICIDES, VIRTUAL CONFERENCE, 6TH JULY 2021

Robin Blake, Editorial Board Member, Compliance Services International

Adrian Dixon

David Cary

Jennifer Lewis

Tristan Jervis

Thorben Looije

Minshad Ansari

This virtual event was held as a follow-up to the inaugural Biopesticide Summit and Exhibition at Swansea University in July 2019, and postponed in 2020 due to the Covid-19 pandemic. Sarah Harding, Communication Director at The World BioProtection Forum (WBF) & Biopesticide Summit opened the event with a few brief words of introduction before handing over to Dr Minshad Ansari, Chairman of the WBF.

Dr Ansari was delighted with the more than 150 attendees already logged into the event with over 300 registered. The WBF was created in 2019 as a non-profit organization to bring together industry and academia for innovation. Dr Ansari thanked the event's supporters – AgBio, Agri Life, Bayer, Bionema, Ecolibrium Biologicals, Koppert Biological Systems, Harry Butler Institute and Sri BioAesthetics, as well as the media partners including *Outlooks on Pest Management*. He reiterated the need for regulatory reform due to removal of chemical pesticides, demands for organic food, limited biopesticide products registered and a lengthy and costly biopesticide registration process (5 years in EU where there are just 60 products available vs. 2.1 years in USA and where over 200 products are already available on market). The US is clearly in a much better place; in Europe, it is too expensive for SMEs and little progress has been made despite the work of the IBMA (International Biocontrol Manufacturers Association) and others. With respect to the biopesticides market share (value) by region, Europe has 27.7% market share (21.3% CAGR) and yet within UK, the CAGR is limited (unlike other European countries) – there are few products available in the market compared to chemical pesticides. The current biopesticide regulation is complex and not fit for purpose (compare 60 vs 200). Industry is facing a serious problem with pest control following the removal of some chemical pesticides, e.g. European cranefly which has caused many problems to the turf industry and has been impacted by the removal of chlorpyrifos. However, Brexit provides opportunities in the UK through government plans to "Build Back Better" by supporting Green Tech. At the EU level, the EU has committed to reducing use of pesticides by 50% (equating to 505 products) by 2030 so there are opportunities here for biopesticides to fill the market.

Dr Ansari finished his introduction by restating the objectives for the meeting: for the speakers to present and debate the need for reform, their visions for a successful regulatory system, and how the WBF is working towards process reform in UK biopesticide regulation.

The first speaker was Adrian Dixon (HSE Chemical Regulations Division) who provided an update on legislation post-Brexit – all the current EU legislation such as pesticide authorisation Regulation (EC) No 1107/2009, Sustainable Use Directive (2009/128/EC) and Machinery Directive (2009/127/EC Amended) are being retained in GB legislation. The main legislative changes introduced from 1st January 2021 included key Statutory Instruments to ensure EU legislation works in the UK – so-called "lift and shift" to turn the legislation into a national system; there are no opportunities to change policy itself. For GB Active Substances (AS) there is now a statutory active substance register created and which is published on the HSE website. The GB review programme is being developed. However, AS approvals can be reviewed at any time should new evidence identify any concerns to human health or the environment. AS approvals due to expire before December 2023 are being extended by 3 years. How the GB Active Substance review programme will work is still being decided and the HSE will seek views on how the programme could work. A new national renewals programme needs to be effective, manageable and proportionate, and efficient without significant additional resource. The HSE is planning on using applications and decisions from other jurisdictions such as the EU but decisions on whether assessments are suitable will be made on a case by case basis. For product authorisations, existing authorisations issued in the UK before the end of the transition period continue to be valid in both GB and NI. Authorisations issued now will specify whether they are valid in GB or NI only, or both. However, there are no changes to the data requirements for the EU. Where possible, the HSE

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will maintain a common MAPP number and allow common labeling (between UK and EU). Going forwards, the national regime will allow all existing AS approvals, plant protection product (PPP) authorisations and MRLs to continue to be valid in GB. The NI regime continues to follow EU rules under the Northern Ireland Protocol. Mr Dixon highlighted the UK Biopesticides Scheme which has been in place since a successful pilot scheme in 2003. The scheme helps provide applicants with free advice and reduced fees, enabling expertise to be developed together with a better understanding of the data requirements, to help applicants through the authorisation process, and with the ultimate aim of increasing biopesticide availability in the UK. Mr Dixon concluded by reiterating that as a regulator the HSE is open to innovation; however, regulators must be satisfied that the pesticide products that are authorised meet high standards of protection and confidence. The Sustainable Use Directive was highlighted as a framework to achieve a sustainable use of pesticides with opportunities for biopesticides and low-risk substances to plug the gap left by the removal off chemical pesticides.

The next speaker was Jennifer Lewis, Executive Director, IBMA, who presented on "What does a successful regulatory framework look like?". Proportionality with respect to specific regulations was highlighted: biocontrol is a nature based solution which does not fit traditional chemistry, it behaves differently. Regulation is focused on biology with specific data requirements but biopesticides need less data which takes less time to evaluate. The IBMA has been working on decision trees for biopesticides and suggested that learning from the European Medicines Agency may be worth considering for biopesticides, e.g. biosimilars, herbal medicinal products and EU herbal monographs. Expert evaluation is key: in the US EPA there is a specific evaluating body with staff with experience in biocontrol evaluation. Having competent authorities with the necessary skills is very important and to allow timely review. Extension of use would encourage broader development and use. Biocontrol focusses on the biocontrol target – it is not crop specific. For example, microbials in Brazil can be used on any crop – only the pest targets must be stated on the label. In France, by comparison, extensions for all crops to be applied can be made under one application for one reduced fee. Both countries have national biocontrol strategies to encourage biocontrol. She highlighted the importance of fast tracking, i.e. getting the products into the market as quickly as possible: 80% of IBMA members are SMEs and therefore a focus on return on investment is very important. In the US and Australia, it takes roughly half the time to register biocontrols vs chemical pesticides in comparison to the EU. Finally, she presented two key enablers for a successful regulation principle for biocontrol: (1) Definitions. There are multiple definitions worldwide. IMBA defines four types of biocontrol, and yet the only European legal definition is in the French Rural Code – therefore definition in legislation is required; and (2) Policies supporting biocontrol innovation: innovation friendly policies that provide underlying support and thus enable regulatory change.

The third speaker was Tristan Jervis, Senior Public Affairs Consultant, who considered that there is a pressing need to reform the UK's biopesticides regulations and approvals process to enhance efficiency and nurture innovation to aid the government's industrial strategy green agenda and science superpower drive. There is a positive backdrop to start with which is very important and a political environment that will be responsive to industry needs. A key government initiative shows real serious commitment to science and innovative industries: (1) National Science and Technology Council (NSTC) established and chaired by the Prime Minister; and (2) New Office for Science and Technology Strategy – based in the Cabinet Office and supporting the NSTC. The goal is to drive forward Whitehall's priorities from the centre to be chaired by a New Technology Advisor (Sir Patrick Vallance) building on the great work with the successful vaccine development system to support the green agenda. Past efforts to reform regulations have been countless but now post-pandemic/post-Brexit there is a great time to press for it. This is where the proposed Public Affairs Campaign comes in with the WBF at the forefront. Our ask is that we take the opportunity to create a tailored UK regulatory system that is faster, simpler, less expensive and better staffed.

The next speaker was Dr David Cary, former Executive Director at IBMA, who presented on "Regulatory reform in the EU". Agriculture is changing and that change should be facilitated. Consumer demand is for healthier produce and a diverse and thriving environment including our agricultural land and its surroundings. However, innovative SME companies are being inappropriately dealt with in the EU. For example, microbial active substances are facing non-renewal procedures whilst chemical active substances are being kept on the market. He questioned "what happens in the meantime?" Should companies have safe and effective microbial PPPs taken from the market until we wait for more appropriate data requirements to be introduced? Should we rely on old chemistry that are candidates for substitution to be providing the solution until we get our act together? Should the EU Commission be allowed to treat microbials as chemistry despite admitting it is totally inappropriate? To help address these concerns, PA Europe have established a task force, the PA Europe Microbial Biocontrol Product Task Force, representing a number of microbial bioprotection producers. The objectives of the task force are to (1) Halt the inappropriate practice being conducted within the regulatory process to prevent the removal of safe and effective microbial products from the market; (2) Reform the regulatory process to facilitate microbial biocontrol products being given timely access to the market rather than the current 10–12 year wait; and (3) Ensure that cost, time and other administrative barriers do not prevent innovative SMEs and/or highly safe and effective niche products from access to the market. Activities to be done by the task force include working with EU institutions particularly the EU Parliament, supporting the work of bodies with regard to appropriate procedures and data requirements (e.g. EU Parliament, OECD, FAO, IBMA), and supporting ongoing good work (e.g. OECD recommendations, IBMA microbial decision tree, experts from academia). Dr Cary stressed that we are very close to microbial biocontrol producers abandoning the EU in favour of other regions. We should not accept empty promises, and avoid false claims of economic collapse and starving populations if agriculture changes – scaremongering does not help. Blown timescales with lack of delivery are not helpful – timescales must be short (i.e. next 12 months), must

be adhered to and must be favourable. We must avoid global competitiveness issues through harmonization and must not just export these issues to third countries. Dr Cary concluded with a message to the regulators and policy makers in the UK: you have a chance to encourage innovation, to facilitate SMEs into a market with safe effective microbial PPPs, and to create benefits for human health and the environment.

The final speaker was Thorben Looije, Director of Valto, who presented on "Registering a biopesticide product: experiences and hurdles". Valto is an innovative Dutch family business specializing in natural crop protection and focused on vegetable crops. Valto's mission is to solve virus problems for growers and help them grow healthy crops. Their best-known product, V10, is used to protect tomato plants from the pepino mosaic virus. However, registration for their innovative solutions is their biggest problem. Mr Looije highlighted that it takes nine years to get a product to market in the EU – even if you can find someone to look at the dossier they cannot start until 2024 (due to high workload), and then it is at least five years to make a decision on a product that he already knows works. The main questions should be is it safe for human health, the environment etc. If it is not a good product the growers will not buy it, there is no need to spend time and money on efficacy trials. Hurdles include time to market that is not doable – farmers want solutions for the next day or the next crop; money – millions of euros is spent to achieve registration on unnecessary studies; regulator expertise is not as good as it should be such that issues, data requirements are poorly understood; requirements differ by country; biocontrol is seen as a pesticide because they are regulated under the same legislation; politics and lobbying are a challenge – too much time is spent debating. The outcome is delay or no registration which is not favorable for growers. In addition, uncertainty and lack of transparency in decision making process makes it challenging for new companies and start-ups to run a normal business. In conclusion, Mr Looije considered that the solution is to create a new registration method for biopesticides altogether – let's create our own EFSA (European Food Safety Authority).

Following a panel discussion, Dr Ansari thanked the speakers, supporters, media partners and attendees, before closing the meeting.