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Open letter to the President of the European Commission Ursula von der Leyen, Executive Vice-President and Commissioner for the European Green Deal Frans Timmermans, Commissioner for Agriculture Janusz Wojciechowski, Commissioner for Health and Food Safety Stella Kyriakides, Commissioner for Innovation, Research, Culture, Education and Youth Mariya Gabriel

Regarding the current discussion of more advanced nonselective herbicide technologies in Europe

Dear President von der Leyen, Dear Vice President Timmermans, Dear Commissioners Wojciechowski, Kyriakides and Gabriel,

Since 2018, Senior Experts Chemistry (SEC), a section of the German Chemical Society (GDCh), led by renowned experts Prof. Dr. Klaus-Dieter Jany and Eckhart Louis has been focused on possible negative outcomes for the agricultural sector and food security associated with EU's total ban of herbicides containing glyphosate after December 2022.

The WHO/IARC-Monograph 112 (March 2015) created widespread uncertainty and a divide in our society about the usage of glyphosate. Environmental associations, politicians, numerous communities, most of media and the majority of the European population are convinced that glyphosate is carcinogenic. As a consequence, political leaders all across Europe are being put under pressure from the society to change legislation in favour of banning glyphosate as soon as possible. For example, the German Federal Government, yielding to the political pressure, limited licensing of glyphosate until the end of 2022. We believe this to be a premature decision since many of the major negative consequences for the European agricultural sector and food security have not been considered.

The SEC have taken a close look at Monograph 112, at IARC Statutory Regulations and at EU and US legal regulations for the usage of herbicides and pesticides. Our literature study concludes, the methodology applied in the IARC hazard assessment processes and in the conclusions provided by IARC in Monograph 112 are highly questionable and contestable in regard to their scientific validity (*Annex 1*).

In contrast to the IARC hazard classification, risk assessments performed by all national competent agencies worldwide considered glyphosate to be safe to use if used correctly. The SEC's academic literature review clearly shows, renowned scientists from around the globe find that glyphosate combined with certain adjuvants, in particular with



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polyethoxylated amines (POEA), triggers distinctly more serious physiological reactions in men and animals than glyphosate by itself. These findings support the EU's ban of POEA in 2016.

We welcome the Commission's decision to allow the Glyphosate Renewal Group to seek renewal of approval of glyphosate post-2022. Whether their application for renewal will be successful is uncertain. This circumstance increases uncertainty for the agricultural sector and European food security since there is currently no effective alternative for herbicides containing glyphosate. What makes this issue even more pressing, rapidly progressing climate change where glyphosate can play an important role in, for example, counteracting soil erosion and controlling soil moisture does not allow for uncertainty. The SEC is aware of European Farmer's frustration as publicly displayed over the past time. Their frustration is triggered by growing concerns about their future resulting from a plethora of unfathomable EU agricultural policies and regulations regarding the usage of herbicides and pesticides in particular. European Farmer's uncertainty and anxiety are underpinned by the vital question: What will be the effective, non-selective herbicide of the near future?

As long as there is no clear answer to the question, whether glyphosate and some of its formulations are cancerogenic or not, have to rely on the official statements issued by regulatory agencies such as EFSA, EPA, and issued by the competent authorities worldwide acknowledging the low-risk levels involved when using herbicides containing glyphosate. Thus the SEC argues, efforts to develop even more effective and safe-to-use active ingredients and formulations (e.g. biodegradation, multifunctional, combat pesticide resistance, minimized quantity required) needs to continue in order to prevent food insecurity and agricultural sector productivity decline.

Decline of European agricultural production, higher dependency on non-EU imports and thus, increasing economic pressure and uncertainty for European farmers are only some of the immediate consequences arising from a total ban of glyphosate as our analysis shows (Annex 2). As demonstrated in Annex 3, agrochemical research has already made far-reaching advancements to current POEA-free-technology leading to remarkable further innovations particularly in the field of adjuvants. In view of this substantial progress, the SEC agrees with the commission and its pursuits of more advanced non-selective future herbicide technologies.

In Annex 4, we argue for the implementation of new organisational processes in order to avoid running into formal regulatory roadblocks in REGULATION No 1107/2009 in general and in Article 7 in particular.

We would like to ask the Commission to initiate and to guide the development process of more advanced nonselective herbicides in Europe. So, it will be ensured, that livelihood and economy of the European agriculture will survive. That is the base of our proposal.



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We thank you for your kind consideration of SEC's proposals, suggestions, and ideas. We are interested in a scientific dialogue with you and relevant EU institutions.

Yours respectfully,

A handwritten signature in black ink that reads "Klaus-Peter Jäckel".

Prof. Dr. Klaus-Peter Jäckel, Chairman of the board "Senior Experts Chemistry" (SEC), section of the German Society of Chemistry (GDCh)

A handwritten signature in blue ink that reads "K. D. Jany".

Prof. Dr. Klaus-Dieter Jany, Member of the SEC board

A handwritten signature in black ink that reads "Eckhart Louis".

Eckhart Louis, SEC – Member

Annex 1 to the GDCh/SEC Open Letter of June 16th 2020 to the European Commission

Regarding the current discussion of more advanced nonselective herbicide technologies in Europe

“Glyphosate is probably carcinogenic to humans (Group 2A)” ??

Not without reason, Monsanto during the past decades has earned a reputation of a bad kind of capitalist acting worldwide and everybody showed understanding when Greenpeace attacked Monsanto vehemently in 2005 already¹.

But does this justify the condemnation of the best researched herbicide ever because this would likely hurt Monsanto? Have therefore farmers all over Europe to be punished by banning Glyphosate which was lauded a once in a century herbicide still in 2008?

We have

- carefully analysed the IARC (International **A**gency for **R**esearch on **C**ancer) statements in their Monograph 112 of 2015². In this Monograph IARC claims that Glyphosate be probably carcinogenic to humans Group 2A.
- carefully analysed IARC’s own Statutes (Preamble)^{3,3a,3b}.
- identified relevant facts insufficiently recognized in Monograph 112 or not considered at all.
- highlighted the numerous statements of scientist independent of Monsanto and of regulatory agencies which came to much more differentiated conclusions about glyphosate⁴⁻¹⁹

Glyphosat ≠ Glyphosate-based formulation

The **A**gricultural **H**ealth **S**tudy (AHS), the main base of Conclusion 6.1 “There is limited evidence in humans for the carcinogenicity of glyphosate”² (page 398) has been inaugurated in 1993 as great US national project. Every participant had to specify from a list of 22 different pesticides in a 21 pages questionnaire those products they had contact with how, when and how frequently, with one pesticide only or with several pesticides at the same time over a period of several years!!² (page 331, left column, Cohort Studies). De Roos et al. in the abstracts of their study²⁰ explain that according to the AHS questionnaire each and every product to be mixed or used containing a glyphosate component was to be termed glyphosate. Sorahan²¹ calls these products simply “a range of Roundup® branded products“. Other publications in the AHS emphasize in the same sense that in reality only glyphosate-based proprietary formulations e.g. from manufacturers Monsanto, Syngenta, Cheminova and many others, but definitely never the active ingredient alone had been used. At least in the initial phase of the AHS also Syngenta’s Touchdown®, competitive proprietary formulation to Monsanto’s Roundup® had been used by the farmers. It’s a fact but not

surprising that Monograph 112 only mentions briefly the alarming analysis of Sorensen et al. "Rapid lethal intoxication caused by the herbicide glyphosate-trimesium (Touchdown)"²². This incident would have shown that not only glyphosate ≠ glyphosate formulation but even glyphosate ≠ glyphosate. Of course, trimesium glyphosate thereafter has been immediately withdrawn in the middle of the AHS.

In order to generate commercially available, storable glyphosate products for agriculture, the various different active ingredients of what is termed glyphosate in the AHS (in² page 321: glyphosate-isopropylamine salt, - mono-ammonium salt, - diammonium salt, -sodium and trimesium salt and also glyphosate acid) must first be transformed in water-based formulations containing emulsifiers, preservatives, defoamers, pH-stabilizers etc. and in particular adjuvants i.e. surfactants which are essential to make the wax-coated plant leaf surface wettable and permeable. Without such transformation in a formulation the active ingredients cannot be absorbed by the plant, are just chemicals not even freely available on market and therefore could not have come in contact with people at all. The powerful surfactants of choice in the US to do this job are still today tallowamine-ethoxylates (POEA, **P**olyoxyethylene**a**mines) which are available after few chemical reactions almost at disposal costs from the tallow piles of the American slaughterhouses. In Europe, POEA are banned since 2016 for health reasons. Since many years groups of scientists independent of Monsanto have discovered and published that there are many significantly weaker physiological effects of glyphosate or even non-existing on the one hand and of glyphosate-based formulations or Roundup® on the other hand⁴⁻¹⁷. Even the Monograph 112 itself concedes under Toxicokinetic data (page 364) e.g. at Gasnier et al. and Larsen et al.: „The Working Group noted that it was not clear whether the effects were caused by glyphosate alone or by adjuvants contained in the formulation.“ Furthermore, Monograph 112 mentions numerous examples of significantly different physiological effects of glyphosate and of glyphosate-based formulations in animals under Non-human mammals in vivo as well as in vitro tests but equally in Humans in vitro experiments. The latter ones are found under 4.2.2 „Receptor-mediated mechanisms“ in the sub-groups „Sex-hormone pathway disruption“, under 4.2.3 „Oxidative stress, inflammation and immunomodulation“ and under 4.2.4 „Cell proliferation and death“. It would have been appropriate from a scientific point of view if Monograph 112 had clearly stated that there are numerous cases of evidence of significantly different reactions in animal in vivo as well as in human in vitro experiments between glyphosate and glyphosate-based formulations containing POEA and other proprietary components.

The criteria for hazard-classification applied in Monograph 112 are questionable from a scientific perspective; the respective IARC-Statutes pre-determine the results

The definition of cancer hazards according to the IARC Statutes reads: "A cancer hazard is an agent that is capable of causing cancer under some circumstances"²³ and "The IARC Monographs identify carcinogenic hazards i.e. those agents having the potential to cause cancer under some circumstances"²⁴. Very obviously, "under some

circumstances” invites the phantasy on the part of the research scientists in terms of methods and/or doses to be used in the studies in order to produce positive results. The Briefing Notes from the IARC Director instruct the Council members that the same understanding shall also apply in their hazard classification job. This is not only an option, it is rather requested by IARC-Statue: „The Monograph evaluations group agents according to the strength of evidence, not their potency” ²⁵. Thus, for IARC’s grouping/classification of hazards it is irrelevant how dangerous actually an agent is but rather how convincingly an evidence of hazard can be presented, under which circumstances ever!

We have to accept this as a principle of proceeding but it prevents openness to the results. Results are pre-determined. The existence of a hazard is a done deal. Three examples may highlight our objections:

1. The publication of N. Benachour and G. E. S  ralini: “Glyphosate formulations induce apoptosis and necrosis in human umbilical, embryonic and placental cells”, *Chem Res Toxicol.*, 22(1):97-105; 2008. The comment of the official Agence Francaise de S  curit   Sanitaire des Aliments of march 26, 2009²⁶ is a devastating assessment of the study starting from inappropriate cell-materials used, to study methods and the results of the study. Interestingly, the study also emphasized the strong impact of POEA present in the formulation.
2. The strongly disputed publication of Paganelli et al: “Glyphosate-based herbicides produce teratogenic effects on vertebrates by impairing retinoic acid signalling” *Chem Res Toxicol*, 23(10):1586-95 (2010). Such effects were observed after injection of glyphosate and glyphosate-based formulations into embryos of chickens and frogs. In the EU Standing Committee meeting of 22-23 November 2010 the Rapporteur Member State, Germany, was requested to comment: “The studies had been performed under highly artificial conditions, extremely different from what can be expected in agricultural circumstances and it is hardly possible to predict adverse effects on mammals on this basis.”
3. The 2008 Case Control Study of Erikson et al. in Sweden²⁷. This study produced remarkably high statistical Odds Ratios and therefore appears as a perfectly convincing evidence of carcinogenicity of glyphosate and other pesticides. However, in contrast to other Studies (e.g. De Roos et al. (2005)²⁰, or Lee et al. (2007)²⁸, Andreotti et al. (2009)²⁹ in which all usual chances of physical contact with the pesticide (pesticide mixing, application method, equipment repairs, equipment cleaning etc., even type of tractor cabin (open, closed, with charcoal filter), frequency of gloves- and cloths changes after contamination/spill and others) have been translated into algorithms for the calculation (Andreotti et al.), the study of Erikson et al. declared in Discussion, page 13: “Use of protective equipment was not asked for which might have been a disadvantage of the study. However, such use would have diluted the exposure and thus bias the result towards unity”. This is very difficult to understand but helps to make Odds Ratios look big.

Overall Conclusion

Scientifically correct and factually unassailable the following formulations in 6. Evaluation would have been:

6.1 *There is limited evidence in humans for the carcinogenicity of glyphosate-based formulations containing POEA and other proprietary ingredients and to a lesser degree of the various chemical variants of the active ingredient glyphosate.*

6.2 *There is significant evidence in experimental animals for the carcinogenicity of glyphosate-based formulations containing POEA and other proprietary ingredients and to a lesser degree of the various chemical variants of the active ingredient glyphosate.*

6.3 *Overall evaluation: Glyphosate-based herbicides have been shown to present potential hazards. In order to avoid that such potential hazards turn into actual risks to the user it is strongly requested to strictly follow the safety instructions on the product labels and to avoid in particular skin contact and inhalation of sprays.*

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- 3 see ²⁾ page 10, right column top
- 3a Briefing Note for IARC Scientific and Governing Council Members Prepared by the IARC Director, January 2018
- 3b IARC Monographs on the Identification of Carcinogenic Hazards to Humans- Preamble
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Anhang 2 zum 1. Offenen Brief an EU, 16.01.2020

Annex 2 to the GDCh/SEC Open Letter of June 16th 2020 to the European Commission

Regarding the current discussion of more advanced nonselective herbicide technologies in Europe

Immediate Consequences of too a rapid complete ban of Glyphosate

From the multitude of respective publications circulating in the internet we quote mostly from

- 1) Steinmann-Theuvsen-Groewitt_Rahmenbedingungen_Glyphosat(5).pdf:
Partial reduction of glyphosate use is possible and desirable, particularly to combat spreading of glyphosate-resistant weed populations; desiccation should be, could be and actually is already limited to very few extreme weed situations; however, a complete ban of glyphosate is undesirable in stubble-cultivation. There is no better alternative to glyphosate to combat difficult to control weed and volunteer grain; under circumstances of elevated risk of erosion (water, wind) there is no better countermeasure than application of glyphosate; in summary publishers do not recommend a complete ban of glyphosate in the EU.
- 2) Glyphosat-Machbarkeitsstudie, Universität für Bodenkultur (BOKU), Wien 02.07.2020 (science.apa.at, Medizin & Biotech)
Under favourable circumstances application of glyphosate may be limited but must not be entirely banned. There are no alternative herbicides existing with comparable spectrum of activity; alternative treatment methods entail severe economic consequences from -9% to – 74% lower contribution margins to the farmer.
- 3) BMEL Fragen und Antworten zu Glyphosat, 29.08.2019: Was sind Alternativen zu glyphosathaltigen Pflanzenschutzmitteln in der Landwirtschaft“
Chemical alternatives to glyphosate may be applied; combination of such products may be necessary to achieve comparable results; if non-chemical methods shall be applied, there exist only mechanical methods (mulching, ploughing, harrowing) or thermal methods (flaming); all mechanical methods are not sustainable and need more fuel; ploughing increases risk of erosion; in areas of increased risk of erosion glyphosate is difficult to replace.
- 4) Oxford Economics “The impact of a Glyphosate ban on the UK Economics, Summary report, June 2017”
Following a ban, farmers will need to adopt more mechanical and labour-intensive means to control weeds.
Will have significant negative impact on UK farmers; increasing reliance on imports; impact of ban not just limited to agriculture. The changes in farming practices as a result of the ban are projected to see agriculture’s contribution to GDP fall some £ 930 million, as the sector’s demand for inputs from British suppliers alters.

Summary of most important consequences:

- 1) Isolation of Europe, no other major world region will abandon the advantages of glyphosate.
- 2) European agricultural output will be lower than previously, farmers will be forced to use more mechanic methods with higher labour cost and higher CO₂ emission.
- 3) Europe will become more and more dependent on imports of herbal foods with maximum glyphosate residual levels different from EU standards.
- 4) No publication of Glyphosate opponents referring to consequences of too a rapid complete ban of glyphosate was found in the internet. The publishers quoted here unanimously do not support such a complete ban.

Anhang 3 zum 1. Offenen Brief an EU, 16.01.2020

Annex 3 to the GDCh/SEC Open Letter of June 16th 2020 to the European Commission

Regarding the current discussion of more advanced nonselective herbicide technologies in Europe

Main innovation efforts during the past few years of the Specialty Chemical Industry in general and Surfactant Manufacturers in particular have mostly targeted towards

- a) biodegradability and syntheses via biochemical processes and
- b) multifunctionality of adjuvants to add more capabilities to formulations.

There are products already approved and available now and others in active development with performance properties, chemists had not been able to even dream of when their imagination was still limited to categories of Glyphosate and POEA. Innovation has made and is continuing to make fascinating progress on the rather new conceptual basis that active ingredients, each one with its specific chemistry require adjuvants equally with specific, tailor-made chemistry in order to create true synergistic units. Thus, it is easier to meet the more and more demanding property profiles of modern pesticide formulations.

There is no lack of new and more advanced products but rather hesitation and even refusal on the part of authorities in charge of approving such new products and product systems. Industry which almost exclusively drives this innovation process regrets that the roadblocks are political in nature and have still a lot to do with the controversies about the IARC-Monograph 112 conclusions. There is still mistrust left toward all kinds of innovation generated by chemical industry. We are convinced that the EU Commission could be helpful to pave the way towards advanced non-selective Herbicide Technologies in Europe.

1. Active ingredients, alternatives to glyphosate

Environmental Associations and Institutions push for pelargonic (CAS 112-05-0) and acetic acid to replace glyphosate as biochemical alternatives (GLOBAL2000.at/glyphosate-alternatives-landwirtschaft); products are approved and commercially available in Austria; “costly to buy but producible by the user” is claimed by GLOBAL2000. Pelargonic acid is also emphasized by (www.ulmer.de/pflanzenbauwissenschaften): “Gegen Unkräuter, Moose und Algen”; Supplier in Austria is e.g. W.Neudorff GmbH KG; For facts about pelargonic acid see: www.Pelargonic Acid-EPA;

Nowadays there are already true biological alternatives to classical chemical crop protection products existing e.g. active ingredients based on living microbial biopesticides e.g. fungal spores and many others; these are mostly used as fungicides at present but herbicidal applications are in focus of product development as well. Sufficient viability of tank-mix systems with such living organisms strongly depend on available multifunctional special adjuvants (see below).

University of Tübingen has recently discovered strong herbicidal efficacy of 7-Desoxyedoheptulose (7dSh). This natural sugar derivate may have the potential

to replace glyphosate in future. R&D on this alternative candidate is in full swing; the problem of too fast biodegradation of 7dSh at present should be overcome in not overly distant future.

2. Advanced new adjuvants including alternatives to POEA

In this area agrochemical development has achieved enormous progress. Since several years already various alkylpolyglycosides (CAS 68515-73-1), amines, coco, alkyl, ethoxylated (CAS 61791-14-8), polyglycerol esters of fatty acids (CAS 79665-93-3) and triethyleneglycol-monobutylether (CAS 143-22-6) are on the market and are being used instead of POEA in commercial glyphosate-formulations and other crop protection products. Special new polyglycerol esters of natural fatty acids with hydrophilic or hydrophobic characteristics have been developed recently to provide most favourable performance combinations for adhesion, retention and drift control (*Product Class Representatives Registered in Germany: 8399-00; 00A137-00; OMRI and FiBL-listed*).

Adjuvants of completely new molecular design based on Trisiloxane technology have been synthesized during the past few years. They are capable to combine several desirable features more of a spray than it had been possible with POEA and the other “classical” adjuvants mentioned above. Good spreading or super spreading, rapid uptake and penetration through the cuticula are beneficial features which operate directly on the leaf surface. Even more important requirements on today’s sprays are improved retention and minimized wash-off to prevent soil contamination. This goes along with improved rainfastness, reduction of driftable particles and minimized overall spray drift. Another positive side effect of all these new adjuvants is the reduction of active ingredient use-rates.

Biodegradable and water soluble liquid but even solid Trisiloxane compounds on solid carriers - molecules you had not been able to think about only few years ago - have been developed recently and are already on the market (*Product Class Representatives Registered in the UK: 0465, in Germany: 86676-00*). They are suitable for all kinds of pesticides in-can and as tank-mix additives but even for solid pesticide formulations which are becoming more important now. Trisiloxan-type adjuvants are the key to extended viability of spray systems with living organisms.

Another group of revolutionary new, completely natural based chemical adjuvants are surfactants based on so called sophorolipids. They are synthesized by fermentation of vegetable feedstock (sugar, natural fatty acids) using natural yeast strains. (*Product Class Representatives Registered in Germany: 8856-00*). Solid actives can be very homogeneously dispersed in low foaming formulations with outstanding adhesion and retention on difficult to wet leaves.

Another biochemical approach: „Adjuvant A-178® an alternative to POEA in Glyphosate-formulations“ is coming from Shanghai Key Laboratory of Chemical Biology, School of Pharmacy, East China University of Science and Technology. This surfactant “is based on coconut shell extracts.”

Very obviously the highly complex chemistry and biochemistry of the various new actives and adjuvants require deep and special understanding and know how. Market

analyses tell us that Europe seems to have still the leading position in this area. This strength should not be sacrificed by ideological or political hostilities.

Annex 4 to the GDCh/SEC Open Letter of June 16th 2020 to the European Commission

Regarding the current discussion of more advanced nonselective herbicide technologies in Europe

In *Annex 1* to this Open Letter we have shown that the Overall Conclusion 6.3 of the IARC-Monograph 112 is not based on unbiased science and Conclusion 6.1 in reality is based on even less than limited evidence of carcinogenicity of Glyphosate in humans. Furthermore, all national authorities worldwide deny cancer risk if Glyphosate is used as intended. Nonetheless political parties in European national parliaments and in the EU parliament ignore the ruling of the respective regulatory agencies and continue to work actively on the complete ban of Glyphosate in Europe as soon as possible.

In *Annex 2* we have reported clear predictions of respected professional analysts that a complete ban of Glyphosate in Europe will render farming unattractive if local conditions make Glyphosate difficult to be replaced. Here, farmers will get out of business. Europe will become isolated and significantly more dependent on imports of plant-based food from other global regions where the unique advantages of Glyphosate are not abandoned. Analysts with macro-economic focus unanimously do not recommend glyphosate-ban as long as alternatives with comparable cost and functional performance are not available.

In *Annex 3* we have identified and specified few products which may have the potential to become alternatives to Glyphosate. But there is a great number of new, multifunctional and highly valuable adjuvants which offer at present already the opportunity to create unique tailor-made pesticide formulations with synergistic effects between active ingredient and adjuvant. Industry however, is not making use of these innovations for the development of new non-selective herbicides specifically as long as the future of non-selective herbicides in general and of Glyphosate in particular is not secure.

Very obviously there is urgency now to prevent Europe from becoming isolated and running into socio-economic problems from. Hunger as consequence of the alarming growth of the world's population will not tolerate emotional extra settlements for Europeans. But Europe is not yet prepared for a complete ban of Glyphosate. Alternatives with comparable cost and functions are still not available at present. However, promising new chemicals and biochemicals to assist in this dilemma do exist already but must be actively seized and converted into better accepted advanced herbicide technologies.

We have studied the procedures of REGULATION (EC) No. 1107/2009, especially of Article 7 "Application" and have come to the conclusion that without political support and unconventional direct involvement of the EUROPEAN COMMISSION it will be hardly possible to make use of these innovations:

- Except for pelargonic acid (see *Annex 3*), registered under "*Finalsan Unkrautfrei*" from producer Neudorff GmbH KG and approved in No 1107/2009 under "*Fatty*"

Acids C₇-C₂₀ there is no other product and producer of a new active ingredient especially designed for non-specific herbicides application. There are rather product candidates worth to be seriously looked at either in the industry but here with other focus as long as future of chemicals for non-selective herbicides is politically unsecure or such candidates are still under development at a University or a scientific laboratory like 7-Desoxysedoheptulose. These situations have no fit to the rules of Article 7 (producer must already exist to make application) and development is still far from meeting the vast number of requirements as by Article 4.

- Experience with Glyphosate plus POEA, but even more first experiences with new adjuvants are tutoring that active pesticide ingredients, each one with its specific chemistry may be combined with adjuvants of equally specific tailormade chemistry to create true synergistic combinations in new final formulations. Such situation makes it difficult to specify what is the isolated active ingredient separate from the adjuvant. But this is the necessary precondition in Article 7.
- Also, it seems inappropriate to simply declare any new non-selective herbicide candidate a new plant protection product formulation in order to make it formally fit for approval by a Member State (Basic stipulation (23), page L 309/3 of REGULATION (EC) No 1107/2009). Such new products most likely will contain new chemical types of adjuvants and/or actives unknown until present in this area. Furthermore, innovations in the area of non-selective herbicides shall be placed on the market all over Europe and not in specific Regions only as by Annex I of No 1107/2009.

Our Proposal

Without new organizational processes preceding the existing rules of REGULATION (EC) No 1107/2009 we do not see a real chance for Europe to overcome the dilemma of becoming the only region in the world without competitive technologies for efficient non-selective weed control. Obviously, the development of such technologies will be a long-term and costly multistep process. If the COMMISSION accepts to take a proactive initiator and leader function in this issue especially in the initial phase, we believe in the chance to be successful.

As a first step the COMMISSION may appoint a Preliminary Examination Board (PEB) of experts from agriculture, chemistry, industry, medical sciences and from authorities for health, consumer protection and environmental protection. The PEB is assigned to first collect by interviews with the agrichemical industry and respective scientific laboratories, by studying all relevant product- and safety literature, field reports, scientific literature worldwide and other chemical-, product- and safety information available referring to the potential product candidates of *Annex 3* and beyond. In a second step the PEB discusses, assesses and finally votes which are the most suitable product candidates (active ingredients and/or adjuvants) and prepares a written evaluation report to be submitted to the COMMISSION in due time. Even if desirable, it will hardly be possible to achieve unanimous conclusions within the PEB. In order to be able to work, the COMMISSION should agree majority decisions among the PEB. All votes pro and contra and thus accepting responsibility by the individual members should be documented in PEB minutes. The COMMISSION checks minutes

and documentation especially in case of disagreements within the PEB and makes sure the appropriate presence of the various groups of interest is maintained. How the consecutive steps may be best phased into the regular processes and rules of REGULATION (EC) No 1107/2009 can only be decided by the COMMISSION. Most likely the industry will be interested in getting actively involved in the further processes if it has been the EU COMMISSION to recommend certain products or components.



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Food and feed safety, innovation
Pesticides and biocides

Brussels,
SANTE.E.4/MW/mb (2020)413823

Dear Professor Jäckel,

Subject: Your letter dated 16 June 2020 concerning nonselective herbicide technologies in Europe, including glyphosate (Our ref: ARES(2020)3143511)

Thank you for your open letter addressed to President von der Leyen, Vice President Timmermans and Commissioners Wojciechowski, Kyriakides and Gabriel, who have asked me to reply to your letter on their behalf.

In your letter you express concerns about possible negative outcomes for the European agricultural sector and food security in the event that the approval of glyphosate would not be renewed beyond December 2022 and on the lack of alternative non-selective herbicides available to EU farmers.

A new renewal process to determine whether glyphosate still meets the approval criteria laid down in the EU legislation on pesticides (Regulation (EC) No 1107/2009) has recently started. An application for renewal of approval of glyphosate beyond 15 December 2022 was submitted by the Glyphosate Renewal Group (GRG) to the Assessment Group on Glyphosate ('AGG' comprised of four EU Member States, France, Hungary, the Netherlands and Sweden) in December 2019, followed by a dossier in June 2020. Further information on the renewal process can be found on the dedicated webpage on Europa: https://ec.europa.eu/food/plant/pesticides/glyphosate_en.

As part of the renewal evaluation, the impact of glyphosate on human and animal health and the environment will be examined, taking into account all available information and the most recent scientific and technical knowledge. Once the AGG has prepared its assessment in the form of a Renewal Assessment Report (RAR), it will be transmitted to the European Food Safety Authority (EFSA) who will launch a public consultation¹ on it. I would encourage you to submit comments during the consultation. All comments will

¹ <http://www.efsa.europa.eu/en/calls/consultations>

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be considered in the subsequent peer review. As for any active substance, renewal of approval will only be possible if the approval criteria are fulfilled for at least one use of glyphosate.

In reply to your concerns about alternatives of non-selective herbicide technologies, I would like to recall that one of the targets of the Farm to Fork Strategy² is the reduction of risks and use, as well as dependency of EU farmers on chemical plant protection products (PPPs). As part of the Strategy, the EU Research Programme will be reinforced to include research and innovation activities to support the achievement of the target. For example, a new Horizon Europe partnership for “Safe and sustainable food systems for people, planet and climate” will put in place a research and innovation governance mechanism engaging Member States and food systems actors from farm-to-fork, to deliver innovative solutions providing benefits for nutrition, quality of food, climate, circularity and communities.

Chemical herbicides can have effects on the environment, non-target organisms, and animal and human health. Therefore, EU and Member State policies seek to reduce reliance on these substances by, among others, designing and implementing more integrated approaches for pest management that at the same time safeguard the competitiveness of agriculture in the EU. Non-chemical weed management techniques range from preventive to curative strategies (e.g. crop rotation, cropping systems, tillage, mechanical weed control, use of alternatives to critical active substances) and cover both the organic and the conventional sectors. Several EU projects have been set up to stimulate such activities including Integrated Weed Management Praise³ (IWMPRAISE) under Horizon 2020.

In your letter, you propose changes to the regulatory framework as laid down in Regulation 1107/2009 in particular the creation of a ‘Preliminary Examination Board’ composed of stakeholder representatives. Please be informed that the Commission has recently published a report on the REFIT evaluation⁴ of the EU pesticides legislation to check whether it is fit for purpose. One of the main findings of the REFIT evaluation is that while the objective of protecting human health and the environment is generally achieved, the full potential is not yet reached, as efficiency of the implementation needs to be improved.

The Commission has identified sixteen areas where implementation need to be improved and has announced a range of actions to, among others, increase efficiency and transparency.

Let me conclude by emphasising that the Commission is committed to developing a sustainable food system to contribute towards achieving the climate and environmental objectives of the Green Deal.

Yours sincerely,

² https://ec.europa.eu/food/farm2fork_en

³ <https://iwmpraise.eu/>

⁴ https://ec.europa.eu/food/plant/pesticides/refit_en

Klaus Berend
Head of Unit



SENIOREXPERTEN CHEMIE
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Frankfurt/Main, May 18th, 2022

Open letter to the *President* of the European Commission Ursula von der Leyen, Executive Vice-President and Commissioner for the European Green Deal Frans Timmermans, Commissioner for Agriculture Janusz Wojciechowski, Commissioner for Health and Food Safety Stella Kyriakides, Commissioner for Environment, Ocean and Fisheries Virginijus Sinkevicius

Regarding the current discussion of more advanced nonselective herbicide technologies in Europe, focus on Surfactants used in Glyphosate Based Herbicides

Dear President von der Leyen, Dear Vice President Timmermans, Dear Commissioners Wojciechowski, Kyriakides and Sinkevicius,

In addition to our statement in an open letter to the EU Commission of 16.06.2020 on the obviously unscientific assessment of the IARC, the herbicide glyphosate probably should have a carcinogenic effect on the human organism, we would like to ask you in another statement of the Senior Expert Group Chemistry (SEC) of the German Chemical Society (GDCh) (see attachment) to direct your focus on the more intensive research of the different formulations of the dosage forms of the herbicide containing glyphosate on the market. By our statement, we would like to support the demands of the Glyphosate Assessment Group (AGG, consisting of representatives from F, NL, HR and S), which has certified glyphosate itself as harmless with regard to carcinogenicity, but recommends that the issue of toxicity of the formulations be further considered. In the face of the Ukraine war and the threat of famine in many countries around the world, it is urgent to obtain clarity on the different glyphosate formulations with regard to their toxicity so that this herbicide can continue to be used to increase the productivity of life-sustaining cereal crops worldwide without harm to life and limb. We therefore ask the Commission to support more intensive research into glyphosate formulations.

Yours respectfully,

A handwritten signature in black ink that reads "Klaus-Peter Jäckel". The signature is written in a cursive, flowing style.

Prof. Dr. Klaus-Peter Jäckel, Chairman of the board "Senior Experts Chemistry" (SEC), section of the German Society of Chemistry (GDCh)



SENIOREXPERTEN CHEMIE
Vorstand
Vorsitzender: Prof. Dr. Klaus-Peter Jäckel

A handwritten signature in blue ink, reading "K.-D. Jany".

Prof. Dr. Klaus-Dieter Jany, Member of the SEC board

A handwritten signature in black ink, reading "Eckhart Louis".

Dr. Eckhart Louis, SEC – Member



SENIOREXPERTEN CHEMIE
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Frankfurt/Main, May 18th 2022

Attachment to the Open letter to the EU Commission

Regarding the current discussion of more advanced nonselective herbicide technologies in Europe, focus on Surfactants used in Glyphosate Based Herbicides

Dear Mrs. President Ursula von der Leyen
Dear Mr. Timmermans
Dear Mrs. Kyriakides DG SANTE
Dear Mr. Sinkevicius DG ENV
Dear Mr. Wojciechowski DG AGRI

The world's most widely used herbicide glyphosate in practice only come in contact with humans, plants and environment by means of Glyphosate Based Herbicides (GBH). Next to the active ingredient glyphosate, all GBH consist of so-called adjuvant packages with surfactants being the most important component thereof. These surfactants make the herbicide spread out and penetrate through the leaf surface.

Dating back since more than two decades, more and more scientific studies have highlighted that such glyphosate-based formulations with highly efficient surfactants often are significantly more genotoxic than glyphosate alone. In the Annex, please find just 10 such examples of scientific studies taken exclusively from the draft AGG-Report, the Commission has recently made available to the public for commenting.

First Robin Mesnage and Michael N. Antoniou brought it to the point in *Frontiers in Public Health*, 2018 Vol. 5, pp 361: "Ignoring Adjuvant Toxicity Falsifies the Safety Profile of commercial Pesticides". Only few months ago the same group of authors (see Annex) reported that EU-, UK- und US- representative GBH-formulations: "cause more biological changes linked with carcinogenesis than glyphosate".

During the recent Glyphosate Renewal Process, the Assessment Group Glyphosate (AGG, consisting of representatives from F, NL, HR and S) clearly stated: "The peer review recognized that the issue of toxicity of the formulations should be considered further as some published genotoxicity studies (not according to GPL or to OECD) on formulations presented positive results *in vitro* and *in vivo*. In particular, it was considered that the genotoxic potential of formulations should be addressed". (page 11 of the October 17, 2019 Pres Submission Meeting documentation)

For reasons we don't know, AGG gave up this request. They rather accepted the glyphosate manufacturer's counterproposal to use just one single "Representative Formulation MON 52276" to represent all Glyphosate-Based-Formulations offered in Europe. This proposal was based on one single sentence in the *EFSA 2019 Genotoxicity assessment of chemical mixtures* rule: "If the assessment of all components of a chemically fully defined mixture results in the conclusion that none of these raises a concern with respect to genotoxicity, the mixture is also considered of no

concern with respect to genotoxicity". However, the surfactants in this reference formulation are protected by trade secrets and hence were not and are not disclosed.

Due to this unacceptable situation we herewith respectfully ask the European Commission to initiate an Investigation Program on the Safety of Surfactants in Glyphosate Based Herbicides. This program should at least roughly classify among the numerous surfactants currently used in commercial GBH in Europe. Just three classes like:

- prohibited (e.g. POEA) or not recommended
- no objections known at present level of knowledge
- preferred at present level of knowledge

would already very much assist the national authorities which, according to EU-Regulation 1107/2009, are solely responsible for licensing Pesticide-Formulations. Also, this would help discourage foreign GBH-manufacturers to enter the European market with Non-State-of-the-Art-Products. Probably, such undertaking will encounter complex surfactant combinations and patent-issues. But public interest and safety concerns should prevail.

Until genetically modified crops will be available on the market which make herbicides unnecessary, agriculture will need at least limited amounts of GBH. European farmers should be sure to buy GBH which present the best possible compromise between efficiency, ecology and economy.

Yours respectfully,



Prof. Dr. Klaus-Peter Jäckel, Chairman of the board "Senior Experts Chemistry" (SEC), section of the German Society of Chemistry (GDCh)



Prof. Dr. Klaus-Dieter Jany, Member of the SEC board



Dr. Eckhart Louis, SEC – Member

With reference to the above explained situation that the safety profile of the active component glyphosate is not the same as the safety profile of a GBH, first please find below the report about threatening recent study results found at EU-, UK- and US reference formulations mentioned before and just 10 examples of scientific studies taken exclusively from the draft AGG-Report. These examples emphasize such additional negative impacts of surfactants and/or they compare different surfactants in this respect.

- 1- R. Mesnage et al.; Comparative Toxicogenomics of Glyphosate and Roundup Herbicides by Mammalian Stem Cell-Based Genotoxicity Assays and Molecular Profiling in Sprague-Dawley Rats; Toxicological Sciences, Vol 186, Issue 1, March 2022, Pages 83-101
- 2- Vol. 3 B.4.4.3. Genotoxicity, pp 293-302; Nagy K. et al. highlighting significant differences between the impacts of ethoxylated etheralkylamine (CAS No. 68478-96-6) in "Roundup Mega" "hygroscopic substances" in "Fozat 480" polyethoxylated tallow amine (CAS No. 61791-26-2) in "Glyphos" to cyto- and genotoxicity in human cells; Environmental research (2019) Vol. 179, No. 108851, pp 1-7
- 3- Vol. 3 B.4.4.16. Public literature referenced in previous CLH report in vitro and in vivo genotoxicity studies pp 374-379; Bolognesi C. et al.; impact of surfactants, in particular alkylsulfate surfactants to various DNA damage in mice
- 4- Vol. 3 B.4.4.16. Public literature referenced in previous CLH report in vitro and in vivo genotoxicity studies page 379; Peluso M. et al.; ³¹P-Postlabelling Detection of Roundup DNA-Adducts were not related to the i-propylamine-glyphosate active ingredient but to another unknown component of the herbicide mixture
- 5- Vol. 3 B.6.5.18.7. Supporting publications p 226; Hao Y. et al. in Journal of Agriculture and food chemistry (2019) Vol. 67 No.41, pp 11346-372; presenting evidence that polyethoxylated Tallowamine promotes autophagy of human A549 cells
- 6- Vol. 3 B.6.6.3.1. Public literature relevant for section B.6.6.1. page 225; Gorga A. et al. in Toxicological sciences (2012) Vol. 127 No. 2 pp 391-402: Roundup Full II from Monsanto Argentina with undisclosed surfactant(s) and K-salt of glyphosate exhibits almost identical effects on Sertoli-cells of rats compared to the glyphosate-salt alone
- 7- Vol. 3 B.6.6.3. Reproductive Toxicity-Information from public literature page 235; Manservigi F. et al. in Environmental Health (2019) Vol. 18 No. 1 pp15; Roundup Bio Flow being identical with MON 52276 of undisclosed surfactant(s) has significantly stronger impact on reproductive outcomes in rats than the Glyphosate i-propylamine-salt alone
- 8- Vol. 3 B.6.6.3. Reproductive Toxicity-Information from public literature page 246; Pham T. et al. in Toxicological sciences (2019) Vol. 169 No. 1 pp 260-271; Roundup 3 Plus from Monsanto Europe with undisclosed surfactant(s) shows significant impact on reproductive parameters in mice compared to glyphosate 99,2% purity
- 9- Vol. 3 B.6.10-2a Overview of relevant but supplementary (category B) articles after detailed assessment page 796; DeFarge N. et al. in Int. J. Environ. Res. Public Health (2016) Vol. 13, pp 246; Co-formulants in GBHs with a broad variety of surfactants tested, incl, APGs (CAS No 383178-66-3), polyoxyethylene-etherphosphates (CAS No. 86130-47-2), polyoxyethylene-alkyletherphosphates (CAS No. 50769-39-6) and others disrupt Aromatase Activity in Human Cells well below levels of the active ingredient alone



SENIOREXPERTEN CHEMIE
Vorstand
Vorsitzender: Prof. Dr. Klaus-Peter Jäckel

- 10- Vol. 3 B.6.10-2a Overview of relevant but supplementary (category B) articles after detailed assessment page 797; Song H-Y et al. in Journal of Korean medical science (2012) Vol. 27 No. 7; substantial differences in cellular toxicities between mixtures of glyphosate and surfactant POEA (Trade name NT 20) and glyphosate and surfactant polyoxyethylene laurylamine (Trade name NT 10)
- 11- Vol. 3 B.6.10-2a Overview of relevant but supplementary (category B) articles after detailed assessment page 816; Mesnage R. et al. in Toxicology (2013) Vol. 313 No. 2-3 pp 122; tests on human cell lines comparing systematically the different toxicities of POEAs with different di-ethoxylate/tallowamine ratios



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Deputy Director General for food sustainability responsible for Directorates D, E, F and G

Brussels,
SANTE/E4/NT/gb/(2022)4721368

Dear Prof. Dr. Jäckel, Prof. Dr. Jany, and Dr. Louis,

Subject: Your letter of 18 May 2022 on the current discussion of more advanced nonselective herbicide technologies in Europe, focus on Surfactants used in Glyphosate Based Herbicides

Thank you for your above-mentioned letter to President von der Leyen, Executive Vice-President Timmermans, and Commissioners Kyriakides, Sinkevicius and Wojciechowski, who asked me to respond on their behalf. In your letter you comment on the necessity to fully investigate the toxicity of glyphosate-based formulations and call of the Commission to initiate an investigation programme on the safety of surfactants in glyphosate-based herbicides.

First, please let me emphasise that the protection of human and animal health, of the environment, and the promotion of scientific research are among our highest priorities. The European Union regulatory framework for plant protection products (PPPs) is among the most stringent in the world. Regulation (EC) No 1107/2009¹ provides that only active substances and PPPs containing them that fulfil the criteria set in this regulation can be authorised for use. All approvals and authorisations are limited in time and must be periodically reviewed so that new scientific and technical developments are fully taken into account.

Regulation (EC) No 1107/2009 sets out a two-step process with the approval of active substances at EU level (following a comprehensive scientific assessment that includes data on the active substance and at least one formulated products), and the authorisation of formulated products by Member States. Before granting product authorisations, Member States must indeed assess the properties of the specific product formulations

¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

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Commission Regulation (EU) No 284/2013² requires that the detailed composition of each PPP is submitted to the competent authorities and that for each formulated PPP the applicant provides data that should allow the assessment of all relevant effects of any co-formulants and certain tests must be conducted with the formulated products themselves. Furthermore, Member States may request additional data on each co-formulant or on the product itself, if deemed necessary. Lastly, the mutual recognition and the zonal authorisation procedures imply that Member States peer-review each other's assessments of PPPs.

Please be also informed that Annex III to Regulation (EC) No 1107/2009³ (as amended by Commission Regulation (EU) 2021/383⁴) lists all co-formulants which are not accepted for inclusion in PPPs – thus corresponding to the first category of substances for which you call in your letter. Those include polyethoxylated tallowamines, whose presence in formulations containing glyphosate had raised concerns over potential negative effects on human health. The Commission is in the process of preparing an Implementing Regulation setting up a process by which Member States can propose further co-formulants to be examined and possibly added to this Annex III and the draft Regulation is currently under discussion with Member States at the Standing Committee on Plants, Animals, Food and Feed. The draft will be subjected to public consultation in due time.

Let me also recall that the process for the possible renewal of approval of glyphosate (currently expiring on 15 December 2022) is ongoing and it is premature to speculate about whether this active substance will remain approved in the future or not. Detailed and up-to-date information on the renewal process is available at our dedicated website⁵.

Once again, let me emphasise that the safety of consumers, human and animal health, protection of the environment, scientific research and technological development, and sustainable and competitive agriculture, are all goals of highest importance for the Commission and its services and we will continue to work towards achieving them.

Yours sincerely,

Claire Bury

² Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 85).

³ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

⁴ Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and of the Council listing co-formulants which are not accepted for inclusion in plant protection products (OJ L 74, 4.3.2021, p. 7).

⁵ https://ec.europa.eu/food/plants/pesticides/approval-active-substances/renewal-approval/glyphosate_en



Risiken erkennen –
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200.25000.0.392323 vom 23.05.2022	30-0301-03-12012462	-26102	08.06.2022	61 / Frau Dr. Franke

Glyphosat - Offener Brief der GDCh an die EU-Kommission

hier: BfR-Stellungnahme

Der mit Ihrem o. g. Schreiben vom 23.05.2022 übermittelte offene Brief der Gesellschaft Deutscher Chemiker (GDCh) an die EU-Kommission vom 18. Mai 2022 wurde im BfR interessiert zur Kenntnis genommen. Wir machen in diesem Zusammenhang darauf aufmerksam, dass das BfR ebenfalls einen gleichlautenden Brief der GDCh am 20. Mai 2022 erhalten hat.

In Beantwortung beider Schreiben teilen wir mit, dass die von der GDCh geforderte intensivere Erforschung und Berücksichtigung der Gesamtheit der Einzelkomponenten von Pflanzenschutzmitteln in der Risikobewertung seitens des BfR grundsätzlich unterstützt wird. Gleichzeitig ist aus Sicht der Risikobewertung und in Übereinstimmung mit der Verordnung (EG) Nr. 1107/2009 die Genehmigungsfähigkeit eines Wirkstoffes getrennt von der Zulassungsfähigkeit von Pflanzenschutzmitteln, die den entsprechenden Wirkstoff enthalten, zu betrachten.

Für den Wirkstoff Glyphosat wurde die Forderung zur Berücksichtigung der Zusammensetzung der Formulierungen im Ergebnis der letzten EU-Wirkstoffprüfung dahingehend adressiert, dass in der EFSA - Conclusion weitere Daten zur Prüfung der Gentoxizität der Pflanzenschutzmittel gefordert wurden (EFSA Journal 2015;13(11):4302) und entsprechende Daten gemäß der Entscheidung der Europäischen Kommission (Review Report SANTE/10441/2017 Rev 2 vom 09.11.2017) anschließend für die (erneute) Zulassung glyphosat-haltiger Pflanzenschutzmittel vorzulegen waren. Von Seiten des BfR wurde diese Schlussfolgerungen aus der EU-Wirkstoffprüfung unterstützt.

Gleichzeitig wurde empfohlen, einen europäischen Diskussionsprozess zu initiieren, um entsprechende Datenanforderungen in der einschlägigen Verordnung (EG) Nr. 1107/2009 unabhängig vom Wirkstoff zukünftig für alle Pflanzenschutzmittel zu verankern, bei denen aufgrund der Kombination von Wirkstoffen oder der Kombination von Wirkstoff mit Beistoffen ein gentoxisches Potenzial anhand der Kenntnisse zu den Einzelsubstanzen nicht mit hinreichender Sicherheit ausgeschlossen werden kann.

Diese Fragestellung wird das BfR u. a. auch im Rahmen der Arbeiten der in der Abteilung 6 neu eingerichteten Nachwuchsgruppe zu „New-Approach-Method-(NAM)-basierte Bewertung von Mischungstoxizitäten“ adressieren.

Im Auftrag

Dr. Tewes Tralau

Dieses Dokument wurde elektronisch erzeugt und gilt ohne Unterschrift.
