ROMANIA
MINISTERUL SANATATII
ST-BIOCIDE INSP
INSTITUTUL NATIONAL DE SANATATE PUBLICA
SECRETARIATUL TEHNIC DE PRODUSE BIOCIDE

General R4BP rules for MSCA Romania (cMS as concerned member state) in NA-MRS cases and all similar cases (Na-RNL, NA-MRS, NA-MAC, NA-MIC, NA-ADC, NA-BBS, NA-BBP, etc.)

For NA-APP or NA-MRP the requirements do not apply for PAR (Product Assessment Report) and rMS (reference member state) authorization. However please send us these documents if the evaluation ended in the rMS and these documents are final versions and authorized already.

Dear Sir/Madam, **Date: 02 November 2019**

This is a general informal message sent to everybody in order to speed up the product evaluation process!

If you did not receive any invoice from us then please reply to the message in R4BP and let us know that there. We are placing also in this message our expectations from you regarding documentation needed when we process your case and other useful information meant to speed up the evaluation processing time.

If anything matches to your situation then act, otherwise please ignore it.

Please read the instructions from below and act accordingly whenever the situation matches to your case:

1- **Invoices and payments**:

1.1. We work with invoices. If you haven't received any invoices from us (R4BP financial bar from case, email, paper, letter, etc.) please let me know here in R4BP in order to make the invoices for you. Invoices amount are based on Romanian legislative act: ORDER No. 870/1170/98/2017 dated July 27th 2017: https://insp.gov.ro/sites/Biocide/public_html/Documente/Biocide/ORDIN_Nr._870_1170_98_2017_din_27_iulie_2017_en.pdf

Please keep in mind as a general rule, that excepting administrative changes, transfer of national authorizations, and the like, you must receive/pay invoices, issued by us, from 3 Romanian authorities (state institutions) as follows:

A. Romanian National Institute of Public Health (abbreviated: INSP – www.insp.gov.ro). Fiscal Code: 26347241; Bank: Treasury of the sector 5(Trezorerie sector 5); Bank Account: RO49TREZ70520E365000XXXX. This might vary so please use it just as pure informative, always check the real invoice.

B. National Environmental Protection Agency Romania (abbreviated: ANPM – www.anpm.ro) Bank: "Activitatea de Trezorerie şi Contabilitate Publică a Municipiului Bucureşti"; Bank Account number: RO88TREZ7005032XXX001110 ; Cod SWIFT/BIC: TREZROBU; Beneficiary: "Agenţia Naţională pentru Protecţia Mediului - CUI 16462898"

C. Institute for Control of Biological Products and Veterinary Medicines (abbreviated: ICBMV- www.icbmv.ro); Unit: I.C.P.B.M.U.V. BUCURESTI; Authorization. HG 6/14.01.1999; 6/54509;

Fiscal Code.: - 4267214; Address: Bucuresti Str. DUDULUI, nr.39 Sector 6; Bank Account: RO37 TREZ 7062 0G33 0400 XXXX; Bank: "Trezoreria Sector 6".

WARNING: Many invoices fail to be paid because you do not fill all the information correctly. Romanian authorities work not with normal banks but with treasury. You must be very careful with that as the treasury does not work with SWIFT or IBAN code but with Fiscal Code instead. Many failures of payments are due to missing the fiscal code! **Romanian treasuries accept only Romanian currency i.e. LEI. Don't pay in USD, euro, pounds**, etc. as your payment will 100% fail.

For administrative changes, transfer of national authorizations, and the like you must pay only one invoice to Romanian National Institute of Public Health (abbreviated: INSP – www.insp.gov.ro). Fiscal Code: 26347241; Bank: Treasury of the sector 5(Trezorerie sector 5); Account: RO49TREZ70520E365000XXXX. This might vary so please use it just as pure informative, always check the real invoice

1.2. If you already received invoices from us then, please confirm us again, here in R4BP, that you paid all the invoices for your case and that no money returned later back to you because any error in spelling payment details (spelling errors getting wrong account number, wrong fiscal code, wrong destination etc.). Please upload in R4BP all the invoices that you received by email or in person from your legal entity in Romania and please upload us all proof of payments. Otherwise please let me know in order to make the invoices for you.

Warning: Generally speaking regarding payments, After uploading the invoices in R4BP, If we do not receive any feedback from you in the next 30 days we will draw the conclusion that you are not interested anymore in solving your case and we will reject/cancel it in R4BP for MSCA-Romania. Regarding evaluation documents the maximum amount of time is 90 days in total for all of them.

2. Documents As a general rule all documents provided to us (MSCA-ROMANIA) by you or your legal entity (LE) via email, CD-ROM, printed papers etc. MUST BE UPLOADED IN R4BP AS WELL WITH NO EXCEPTION, no matter what institute is about (INSP, ANPM and ICBMV)! This include the history of product all authorizations, annexes and appendices, etc. R4BP must in electronic format have all the documents used for evaluation of your dossier with no exception. Depending of the confidentiality of your document you can set it as "restricted" or "restricted for authorities" and then your document will have a special care in using it and it will not be seen by any other company or go public through ECHA Dissemination Tool.

WARNING: If the rMS product owner does not want to give you any specific document for your case for MSCA ROMANIA as it is strictly confidential then you must ask him/her to send it us in R4BP as "restricted for authority". They can do with an ad-hock communication from our MSCA Romania case number and when uploading the document to be careful to set its permission as "restricted for authority". In this case we can see it but you as LE cannot see it. Please check the latest ECHA R4BP manual for industry in order to learn more about that and how to do it from your industry side! **https://echa.europa.eu/ro/support/dossier-submission-tools/r4bp/biocides-submission-manuals**

3. Case or asset withdrawal

If you want to drop the case then please do it from your side through R4BP for industry by case withdrawal! In R4bp there is the asset cancelling of national authorization (NA-CAT) or case withdrawal. Please check the latest ECHA R4BP manual for industry in order to learn more about that and how to do it from your industry side! https://echa.europa.eu/ro/support/dossier-submission-tools/r4bp/biocides-submission-manuals.

WARNING: If for the same product you applied for both/all: NA-MRS and NA-MRP or NA-APP please drop the NA-MRP an Na-APP. This will save you the money for 3 invoices payment and will prevent further issues and payments in R4BP. One product must have only one UUID in R4BP. It is

the same like you as a person: you cannot have 2 passports or to driving license for the same country in the same time with 2 personal social security numbers! In R4BP this will create 2 different assets for the same products and will trigger in the future 2 NA-REN, NA-MAC, NA-MIC, NA-MIC, NA-ADC, NA-MRG, etc. a lot of money and work spent in waste! So please drop the case/asset if this case matches to your product and do it ASAP for the one coming with/from NA-MRP. Keep only the NA-MRS and the asset coming from that!

4. **Legal entity visits to the Secretariat of the Romanian National Commission of Biocidal Products (abbreviated - ST-CNPB) from the Romanian National Institute of Public Health (abbreviated: INSP)**:

If you already picked up any authorization certificate or any other appendix or annexes to it from us then please scan it in pdf format and upload it in R4BP in order to close your NA-MRS case. Please note that Authorization certificate it is a public document in R4BP after Evaluate & Decide task. It shall not contain any confidential data. Confidential data must be kept inside annexes and shell be set in R4BP as confidential document.

5. Case status in R4BP:

If your MSCA-Romania case number, has no uploaded documents or they are less that those from the rMS(reference member state), then we mandatory need also them uploaded documents for MSCA-ROMANA case if they apply for Romanian evaluation and country profile by using the following rules:

According with Romanian legislation in order to proceed with analysing of your dossier our chemistry experts' compulsory need some of your rMS documents translated into Romanian and English language. They are:

- **Your complete SPC XML file**, i.e. please upload a full SPC with all the data in Romanian language included and do not send us dummy files with minimum content. SPC XML is not a simple translation of the SPC XML file from the rMS. It must reflect your targeted product for our country Romania including market aria, name and trade names posed on our product labels in shops and supermarkets, etc., Please be careful when you are making the SPC XML file. It must be validated by R4BP upload system at EVALUATE & DECIDE Task. If you make the SPC XML file offline on your computer then you risk that your file even looks complete with all data and information in it still to be rejected in the validation process in upload in R4BP. Therefore please use only IUCLID and SPC editor from ECHA website: https://r4bp.echa.europa.eu/spc/#!/editor
- Your product SDS (security data sheet) translated into Romanian language
- Your product CLP (label) translated into Romanian language
- Your product PAR (product assessment report) translated into English language. Warning: Sometimes the rMS state does not want to place PAR in the cMS case arguing that its LE in cMS is not allowed to see PAR at all. In this case you must ask your rMS asset owner to place the PAR to MSCA-Romania as "Restricted for Authorities". In this way MSCA Romania can see the PAR but you can't!
- Your product valid authorization translated into Romanian and English language
- Your letter of access translated into Romanian and English language
- Your supporting documents translated into Romanian and English language
- Your IUCLID dossier
- Your letter/supporting document for your Legal Entity or the product distributor who requires its company name on the product authorization. SPC XML file it is not enough, we need a separate statement signed and stamped from you approving that!
- Any other relevant documents for evaluation in our country translated into English language. Please take in account efficacy of your product on Romanian land and our specific country conditions who might vary because of the relief and other natural geographic conditions!

WARNING: ***All the above mentioned documents must fit each other. This means that all technical data and specifications must correspond among documents. For instance you cannot have one value of concentration or PH in SDS and a different one in SPC, PAR or Authorization! All the obsolete documents must be rewritten and updated in order to be synchronized with PAR, SPC and product authorization. Even them (PAR, SPC and Authorization) must be match/fit each other regarding specifications.***

Please make sure that in the SPC XML and R4BP case there is the active substance, product type stated, trade names, etc! The case cannot go on without it! Check your SPC XML for that! Please also fill all the relevant information in R4BP including your Romanian market distributors, LE, emails, phone numbers, etc.

The Romanian legislation asking you for Romanian version of your documentation is "DECISION No. 617 dated July 23rd 2014 on establishment of institutional framework and of measures for enforcement of Regulation (EU) no. 528/2012 of the European Parliament and of the Council of May 22nd 2012 concerning the making available on the market and use of biocidal products"

From there I mention you the following:

" ART. 6 (1) Biocidal products are placed on the market and used within Romania only if:

a) they are authorized as per Regulation's provisions or if they are licensed as per provisional measures set forth in art. 89 para. (2) of Regulation;

b) are accompanied by labels and material safety data sheets in Romanian.

(2) All documents needed for authorization of a biocidal product must be submitted both in Romanian and English. "

This legislative act is translated in English and it is available online on our web-site at:

http://www.insp.gov.ro/sites/Biocide/public_html/Documente/Biocide/HG_617_2014_EN.pdf

Therefore you must upload all the above mentioned documents for MSCA-Romania case number

Warning: Generally speaking regarding requested documents. Asking for documents in the validate task or Evaluate & Decide Task, then , if we do not receive any feedback from you in the next 90 days we will draw the conclusion that you are not interested anymore in solving your case and we will reject/cancel it in R4BP for MSCA-Romania. According with the R4BP manual and BPR regulations regarding request for evaluation documents the maximum amount of time is 90 days in total for all of them.

Normally, at each request of additional information I will give you a reasonable time to do that of let's say 30 days. If you are in trouble and you need extra more time please inform us regarding time extension need and prolonging deadline. Unfortunately sometimes the deadline might be shorter when assets expire and we must hurry up to avoid it.

6. REGARDING SPC:

SPC XML file is the heart of ECHA IT-Tools and R4BP. This file ensures interoperability among different ECHA IT Tools (IUCLID, R4BP, Dissemination Portal, etc.). Therefore anything wrong in SPC XML will propagate like a disease to other IT Tools. SPC XML file will be public after the R4BP EVALUATE & Decide task, so please make sure to not place any confidential information in it. Use appendix, annexes for product assessment and whatever you like for confidential information but not SPC XML file. It is your responsibility to make sure that any confidential data from your product it is not going public through SPC XML file and accordingly next to the Public Dissemination Tool on ECHA website!

According with Romanian legislation SPC XML MUST BE IN ROMANIAN LANGUAGE, FOR MARKET AREA: Romania SO YOU MUST PROVIDE IT IN ROMANIAN ASAP. IT MUST COMPLY WITH THE FOLLOWING RULES:

The product name from Romanian authorization and all the trade names for your product (if any) must 100% match the SCP XML file AND MUST BE FOR MARKET AREA: Romania. The SPC XML file is not just a simple translation in Romanian language of the SPC XML file from reference member state. Unfortunately this is not what I see in most applications, and therefore you must make sure carefully that your SPC XML file must comply with that. Otherwise your SPC XML file must be amended ASAP in order to fulfil this requirement. If you want other tradenames or product name you must apply for administrative changes (NA-ADC). If you consider that this is in error you or your legal entity in Romania must contact The Secretariat of the Romanian National Commission of Biocidal Products (abbreviated - ST-CNPB) from the Romanian National Institute of Public Health (abbreviated: INSP) and to check out why this matter is happening.

The above policy apply to all SPC XML content. All its content must fit to Romanian authorization, reference member state authorization, SPC and PAR regarding basic features, otherwise it cannot be called mutual recognition.

6. REGARDING contacting us

I am an IT (Computer Science) engineer and *I do not have legal background in chemistry, medical, environment or veterinary evaluation (toxicology, efficacy, environmental human health protection, veterinary protection) of your product at all.*

Therefore, regarding further email replies, according with my background I can help you only with IT matters and administrative tasks in R4BP regarding software issues (validation errors, SPC problems, etc.) My email address is: catalin.oprea@insp.gov.ro.

For any other matters regarding legislation and dossier stage in acceptation, validate and evaluation & decision or processing please write further email requirements to our Biocides Secretariat on biocide@insp.gov.ro ; or to our Biocides National Helpdesk in Romania to: helpdesk.biocide@insp.gov.ro

ECHA Helpdesk (https://echa.europa.eu/contact/bpr) and MSCA-Romania Helpdesk (helpdesk.biocide@insp.gov.ro) can help you regarding all the legislative questions.

If you have any legal Entity in Romania they can personally contact us during our public hours according to the following schedule: Monday to Thursday: 10.00-12.00;

Regarding your further email replies to my email inbox: catalin.oprea@insp.gov.ro, according with my background I can help you only with IT matters and administrative tasks in R4BP regarding software issues (validation errors, SPC problems, etc.).

If you have a legal entity in Romania, then they can also contact us by visiting us during working hours. Our address is: Dr. Leonte Anastasievici Street, No.1-3, Sector 5, Bucharest, Post code: 050463, Romania; Secretariat email: biocide@insp.gov.ro; Helpdesk email: helpdesk.biocide@insp.gov.ro; Phone: (401) 021 318 36 20 extension: 156/158; Fax number: (401) 021 311 86 20; Working hours with the public: Monday to Thursday: 10.00-12.00;

Best regards and sincerely,

MSCA ROMANIA

Eng. Catalin Gabriel Oprea

ECHA MSCA/MNI INSP Romania User

The Secretariat of the Romanian National Commission of Biocidal Products (abbreviated - ST-CNPB) from the Romanian National Institute of Public Health (abbreviated: INSP),

Web-site: http://insp.gov.ro/sites/Biocide/public_html/index.html

Address:
Dr. Leonte Anastasievici Street, No.1-3, Sector 5
Bucharest, Post code: 050463, Romania
Secretariat email: biocide@insp.gov.ro;
Helpdesk email: helpdesk.biocide@insp.gov.ro
Phone: (401) 021 318 36 20 extension: 156/158
Fax number: (401) 021 311 86 20
Work with the public:
Monday to Thursday: 10.00-12.00;

My own personal document disclaimer:

Please note that this document is meant to help you in your work and to faster the evaluation time. It reflects my solely personal competent and specialized opinion as an employee of INSP according to my background, my job description and my skills as an IT & electronics M.Sc. engineer and specialist and according to training, attributions and responsibilities to ECHA as the nominated person as a security officer and users administrator of ECHA token users. Any other opinions regarding legislative or chemical or in areas other than my professional training and qualifications are purely indicative and strictly personal advice's, based on my work experience in the field at work. Therefore, if the scope of this document is out of my professional training framework then it might may contain involuntary errors but unwanted or unintentional errors, with blurry or incomplete solutions. This opinion is meant to help you in your work based on my strictly personal best practices. This is its main purpose as a stated target. Any authorized competent counsel in fields other than my professional qualifications must be obtained only from my colleagues who are specialists and have these qualifications in their job description and training. For advice outside my area of competence, please contact the Secretariat of the National Biocidal Products Commission at: biocide@insp.gov.ro or for regulatory and procedural questions, please contact our Helpdesk Biocide Service at: helpdesk.biocide@insp.gov.ro

Warning: This document does not reflect the official opinion of my organization (INSP). Therefore if you are searching for any organization opinion, according to our internal procedures and regulations then you must get it by requesting it as a dull printed form with stamp, registration number and signatures of the leadership of the Biocides Secretariat, or from the Romanian National Commission of Biocidal Products and senior management of my organization or the competent authority (Ministry of Health http://www.ms.ro/organizare/directia-generala-de-asistenta-medicala-si-sanatate-publica-2/). That is why our legislative advice is purely indicative and is meant to help you understand and know the Romanian or European (EU-EEA) legislation and its methodological norms. My organization (INSP), according to the law, has no legislative powers. As far as biocidal legislation is concerned, INSP as an organization is not a Competent Authority (MSCA), but a National Mandated Institution (MNI) by the Ministry of Health (MSCA) to apply this legislation. The Ministry of Health is the Competent Authority and the Legislative Forum. Therefore, none of the INSP employees' advice may change, modify, trade or amend the legislation in force. We cannot negotiate the legislation in force and we cannot even envy the law in any way. This is illegal. For such requests regarding legislative vaccinations, exceptions or proposals for change, please address directly to the competent authority (Ministry of Health), which is the body of the state or to a similar or superior institution (Government of Romania, other ministries, etc.). As far as the legislation in force, although I know English at a professional level, I do not have the legal permission to translate legislation, as I am not a legally authorized translator empowered to translate the law. If, in my work, I help you to translate some passages from legislation, this does not mean that other passages or articles can be ignored, omitted, or less important in their application. Legislation or normative acts are unitary, indivisible and cannot be censored or simplified. That is why I or my colleagues cannot confirm the translation or the application of some passages. The legislation in force applies entirely and not on passages or articles of legislation. For translating legislation, please contact an authorized translator.