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Life PHARMA DETOX

Demonstration of an innovative method for the detoxification of pharmaceutical wastewater from pharmaceutical facilities

Deliverable A.2: Tender And Permit Documents

Date: 05/2026

Coordinating Beneficiary

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2	09/2025	2nd Final Version (Addition of permit requirements for the pilot installation at the Medochemie premises)	Eleni-Alexia Giouni, Maria Kyriazi
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Disclaimer

The information included herein is legal and true to the best possible knowledge of the authors, as it is the product of the utilization and synthesis of the referenced sources, for which the authors cannot be held accountable.

Abstract

This report was developed within the framework of the co-financed European LIFE-Climate program to support the tender preparation for redesigning and rebuilding the existing plumbing systems in and around the Medochemie B manufacturing facilities, specifically at the Oral Penicillin, Injectable Penicillin, and Ampoules plants in Cyprus. This report serves as Deliverable A.2.

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Table of Contents

EXECUTIVE SUMMARY **6**

1. INTRODUCTION **6**

1.1 Scope and purpose 6

1.1.1 Technical drawings for existing plumbing system modifications 6

1.1.2 Tender document for existing plumbing system modifications 6

1.2 Summary of approach 6

1.2.1 Construction of the pilot system 6

1.2.2 Re-structuring of the plumbing system 7

1.2.3 Main points of the tender procedure 7

1.3 Response to EU Monitor's Comment: Second pre-financing payment– Payment letter – Issue 1: Treated Water Reuse under Regulation (EU) 2020/741 13

List of Figures

Figure 1*: Existing plumbing system of Medochemie B (Oral Penicillin's plant, Injectable Penicillin's Plant, Ampoules) in Cyprus.* 9

Figure 2: Proposed plumbing system of Medochemie B (Oral Penicillin's plant, Injectable Penicillin's Plant, Ampoules) in Cyprus. 10

Figure 3: *Factory layout and container location* 11

Figure 4 Permit requirements for the pilot installation at the Medochemie premises 12

Figure 5 *Official technical guidance from the Ministry of Agriculture, Rural Development and Environment of the Republic of Cyprus on the water reuse potential of the PHARMA-DETOX treated effluent under Regulation (EU) 2020/741.* 14

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Executive Summary

The present report was prepared in the framework of the co-financed European LIFE-Climate for the tender preparation for the redesign and rebuilt of the already existing plumbing system in and out the manufacturing plants of Medochemie B (Oral Penicillin's plant, Injectable Penicillin's Plant, Ampoules) in Cyprus.

1. Introduction

In this report we summarize the activities taken for the tender preparation for the redesign and rebuilt of the already existing plumbing system in and out the manufacturing plants of Medochemie B (Oral Penicillin's plant, Injectable Penicillin's Plant, Ampoules) in Cyprus.

1.1 Scope and purpose

1.1.1 Technical drawings for existing plumbing system modifications

Initially the existing plumbing system was evaluated in terms of wastewater generation. After the evaluation a modification drawing was prepared summarizing the required modifications to enable us collect contaminated wastewater with pharmaceutical ingredients. This proposed drawing forms the core of the tender document to be prepared.

1.1.2 Tender document for existing plumbing system modifications

The tender document prepared for this project are intended to be used for the LIFE PHARMA-DETOX project for Medochemie LTD facilities: Oral Penicillin's plant, Injectable Penicillin's Plant, Ampoules Plant

1.2 Summary of approach

1.2.1 Construction of the pilot system

It's essential for Medochemie to ensure that the selection process for the construction of the sub-system adheres to internal procurement policies and standards. This includes evaluating potential suppliers based on their qualifications, experience, and ability to meet project requirements within the specified budget and timeline. Additionally, maintaining transparency and fairness throughout the selection process is paramount to uphold integrity and promote trust among stakeholders. By carefully managing the procurement process, Medochemie can mitigate risks, achieve cost-efficiency, and ultimately deliver a high-quality sub-system prototype to meet its objectives.

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Given that the construction cost for the sub-system is expected to remain below €135,000, Medochemie is not required to undergo the formal procedure of a Published Open Public Tender for the prototype construction.

1.2.2 Re-structuring of the plumbing system

As a first step a study was performed, and technical drawings were generated for the required modification to have a separate stream of wastewater contaminated with pharmaceutical products and non-contaminated waste water with pharmaceutical products for the three plant's under study (Oral Penicillin's plant, Injectable Penicillin's Plant, Ampoules) in Medochemie Facilities in Cyprus. The technical drawings prepared are attached to the references section of this report (*Figure 2 and Figure 3*)

1.2.3 Main points of the tender procedure

The next step was the generation of a tender document and the call for offers for the required activities. In the tender document all the technical specifications were listed in terms of materials to be used and specific procedures or clarifications to be followed during the works execution.

Medochemie assumes the responsibility of procuring separate parts from various suppliers, with a primary focus on ensuring the quality and quantity of purchased products and services while minimizing adverse environmental and occupational health and safety impacts. Supplier selection and evaluation criteria encompass several key aspects:

- Product Quality: Suppliers must demonstrate a consistent ability to deliver products that meet the required quality standards. This includes providing evidence of technical competence and preferably furnishing references attesting to their quality track record.
- Delivery Time: Timely delivery is paramount to the project's success. Suppliers are expected to commit to and adhere to agreed-upon delivery schedules to ensure uninterrupted production processes.
- Competitive Pricing: Pricing competitiveness plays a crucial role in supplier selection. Medochemie will evaluate suppliers based on their pricing structures to ensure optimal value for the investment.
- Environmental and Occupational Health and Safety (EOHS) Compliance: Suppliers must adhere to stringent environmental and occupational health and safety regulations. This includes obtaining relevant certifications such as ISO 14001, ISO 45001, and any other applicable standards to mitigate negative impacts.

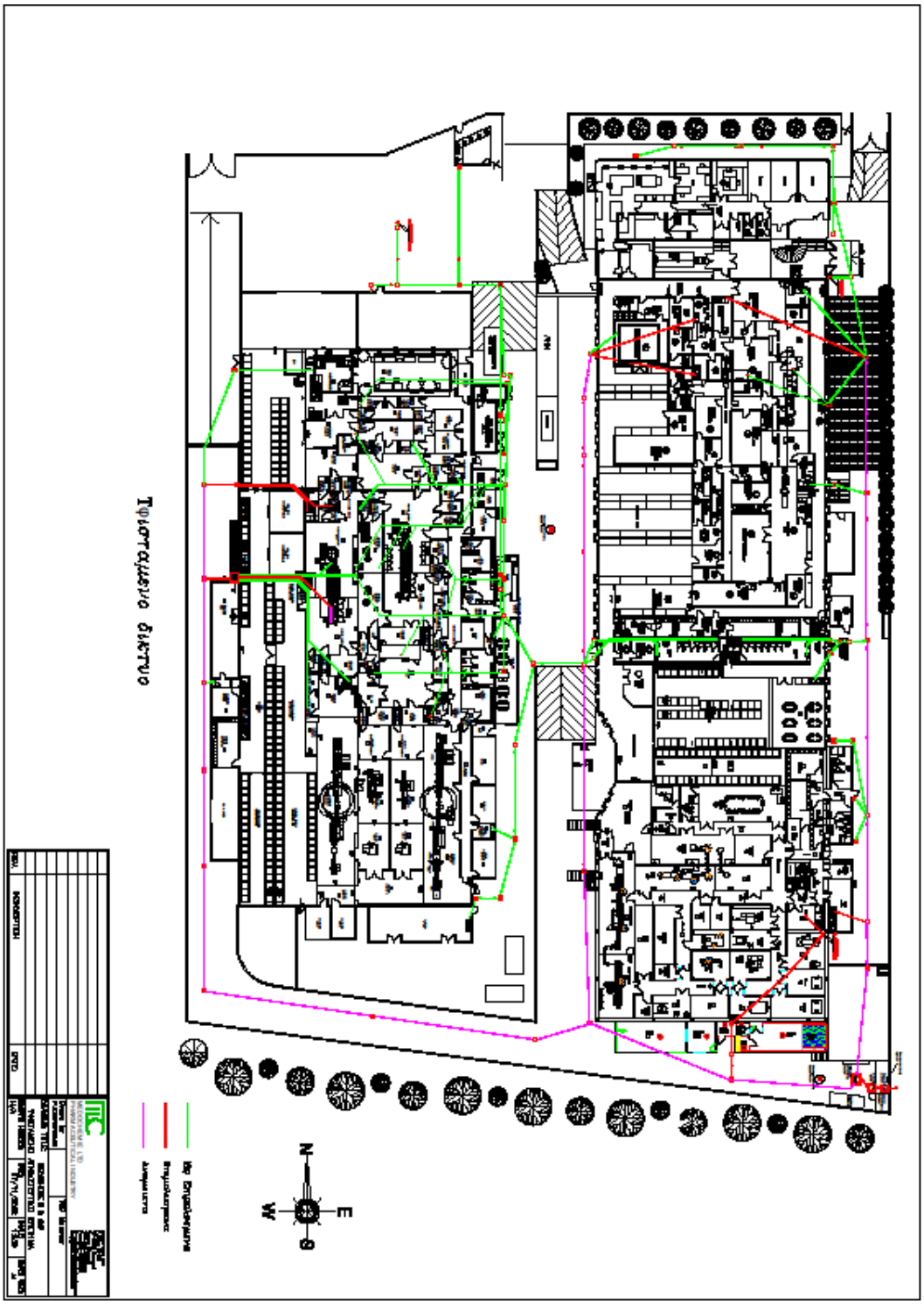
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- Certifications and Professional Competence: Suppliers are required to possess necessary certifications, including but not limited to ISO 9001, ISO 14001, ISO 45001, and VCA* certificates, as well as certificates of professional competence where applicable.
- Documentation: Preferably, suppliers should provide comprehensive documentation pertaining to the products being supplied. This documentation aids in ensuring transparency, traceability, and compliance with project requirements.
- Brand and Product Alignment: Suppliers are expected to provide products and brands that align with client specifications and standards. This ensures compatibility and consistency throughout the prototype development process.

Based on these criteria, Medochemie will meticulously assess potential suppliers to identify the most suitable candidates for partnership, thereby ensuring the successful execution of the project objectives.

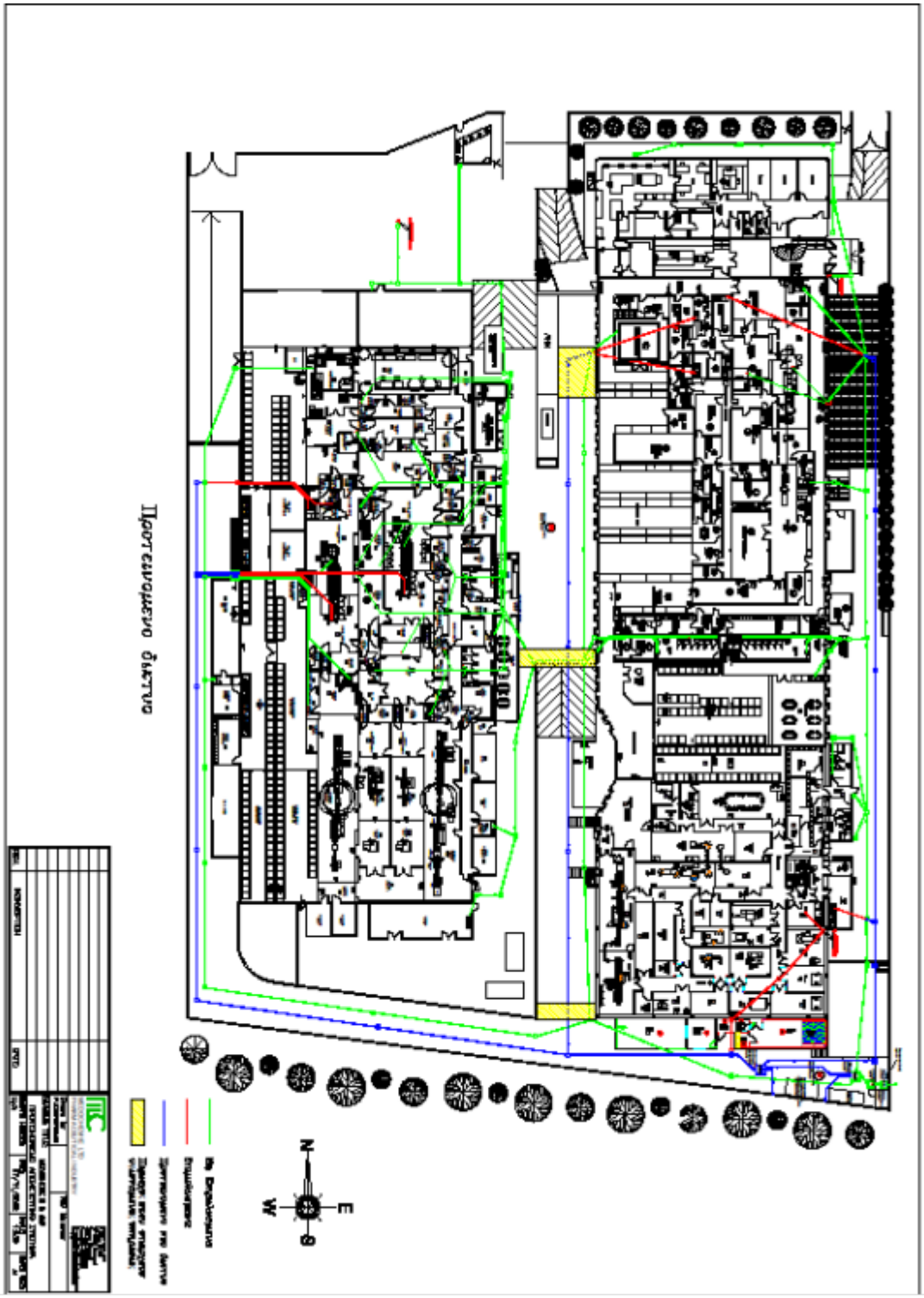
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Figure 1*: Existing plumbing system of Medochemie B (Oral Penicillin's plant, Injectable Penicillin's Plant, Ampoules) in Cyprus.*



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Figure 2: *Proposed plumbing system of Medochemie B (Oral Penicillin's plant, Injectable Penicillin's Plant, Ampoules) in Cyprus.*



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Figure 3: *Factory layout and container location*

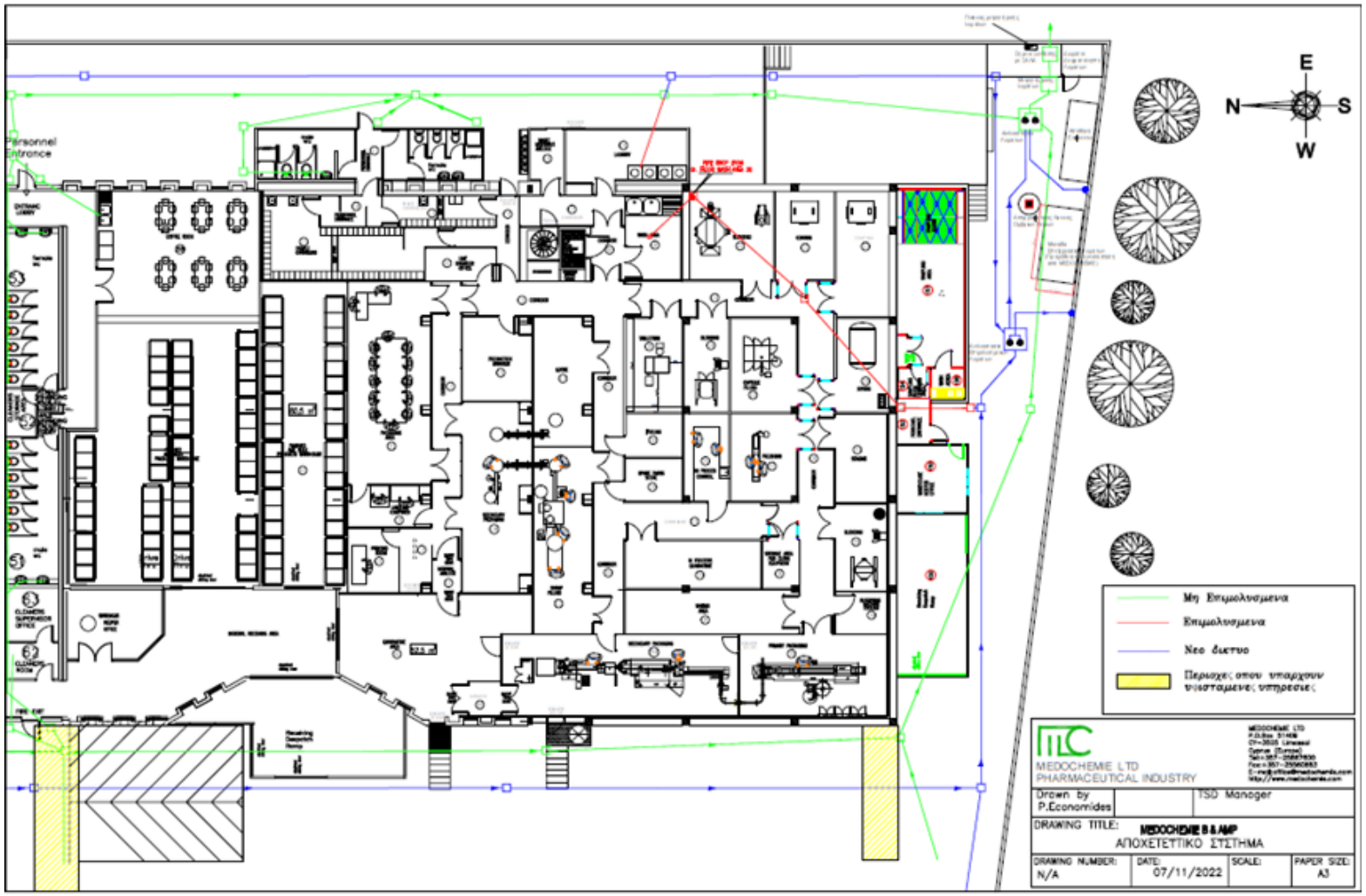


Figure 4 *Permit requirements for the pilot installation at the Medochemie premises*

ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ

ΥΠΟΥΡΓΕΙΟ ΓΕΩΡΓΙΑΣ, ΑΓΡΟΤΙΚΗΣ ΑΝΑΠΤΥΞΗΣ ΚΑΙ ΠΕΡΙΒΑΛΛΟΝΤΟΣ

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20 Μαΐου 2025

ΜΕ ΗΛΕΚΤΡΟΝΙΚΟ ΤΑΧΥΔΡΟΜΕΙΟ

Διευθυντή εταιρείας
Medochemie Ltd

Ερευνητική Μονάδα για Μικρή Πειραματική Εφαρμογή Επεξεργασίας Υδατικών Φαρμακευτικών Αποβλήτων

Αναφορικά με το πιο πάνω θέμα και σε συνέχεια της επιστολής σας με ημερομηνία 04.04.2025, ενημερώνεστε ότι το Τμήμα Περιβάλλοντος δε φέρει ένσταση για τη δοκιμή και τη λειτουργία της μικρής, πειραματικής μονάδας Life Pharma Detox σε μια από τις εγκαταστάσεις της εταιρείας Medochemie Ltd στη Λεμεσό.

Ωστόσο, μέχρι να ολοκληρωθεί η μελέτη και να αποδειχθεί ότι η ποιότητα του επεξεργασμένου νερού το καθιστά κατάλληλο για επαναχρησιμοποίηση για σκοπούς άρδευσης, καθαρισμού, ψύξης κλπ., θα πρέπει να διασφαλιστεί ότι τα υγρά απόβλητα που θα προκύπτουν θα μπορούν να διοχετεύονται στο αποχετευτικό δίκτυο μαζί με τα υπόλοιπα υγρά απόβλητα της εταιρείας. Για το λόγο αυτό θα πρέπει να εξασφαλιστεί και σχετική έγκριση από τον ΕΟΑ Λεμεσού. Σε αντίθετη περίπτωση θα πρέπει να συνάψετε και να προσκομίσετε συμφωνία με αδειοδοτημένη εγκατάσταση που θα παραλαμβάνει το συγκεκριμένο ρεύμα υγρών αποβλήτων.

Για οποιεσδήποτε διευκρινίσεις είμαστε στη διάθεσή σας.

Με εκτίμηση,

Άντα Γεωργάκα
για Διευθυντή

1.3 Response to EU Monitor's Comment: Second pre-financing payment– Payment letter – Issue 1: Treated Water Reuse under Regulation (EU) 2020/741

In response to Issue 1 raised by the EU monitor, the project team received official technical guidance from the Ministry of Agriculture, Rural Development and Environment of the Republic of Cyprus. The correspondence confirmed that, since the primary input for the pharmaceutical washing processes at Medochemie consists of high-quality potable water supplied by the municipal water network, the treated effluent produced by the PHARMA-DETOX system after membrane separation is expected to be of comparably high quality, containing only trace concentrations of pharmaceutical compounds.

The Ministry's guidance referenced Regulation (EU) 2020/741 on minimum requirements for water reuse, which establishes four irrigation water quality categories (A to D). Category A — the highest quality class under the Regulation — covers all food crops consumed raw, including root vegetables, permitting all irrigation methods. The minimum quality criteria for Category A are: E. coli (≤10 cfu/100 mL), BOD_5 (≤10 mg/L), total suspended solids (≤10 mg/L), turbidity (≤10 NTU), and, where applicable, Legionella spp. and intestinal nematodes. Based on the measured physicochemical and microbiological quality of the RO permeate produced by the PHARMA-DETOX pilot system, the treated water meets the requirements of Category A in full.

Regarding pharmaceutical compound residues, the Ministry confirmed that trace pharmaceutical substances are currently subject to monitoring only and are not included in the binding minimum quality requirements under Regulation (EU) 2020/741. The catalytic treatment stage of the PHARMA-DETOX system achieves high removal of these compounds: influent API concentrations of 27.5 mg/L are reduced to 3.3 mg/L in the RO permeate (88% removal), with further reduction to below 1.9 mg/L after catalytic treatment of the concentrate stream (overall removal exceeding 97%).

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Figure 5 *Official technical guidance from the Ministry of Agriculture, Rural Development and Environment of the Republic of Cyprus on the water reuse potential of the PHARMA-DETOX treated effluent under Regulation (EU) 2020/741.*

From: Anastasis Christou <achristou@ari.moa.gov.cy>
Sent: 17 March 2025 12:58
To: Christakis Sergides <christakis.sergides@medochemie.com>
Cc: 'Panagiotis Dalias' <pdalias@ari.moa.gov.cy>
Subject: RE: Information

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Αγαπητέ Δρ. Σεργίδη,

Από την στιγμή που χρησιμοποιείτε νερό καλής ποιότητας από την υδατοπρομήθεια για το ξέπλυμα, το ανακτημένο νερό από την επεξεργασία αναμένεται να είναι επίσης καλής ποιότητας, εμπλουτισμένο με ίχνη φαρμακευτικών ενώσεων.

Παραπάνω σας επισυνάπτω το νέο Ευρωπαϊκό Κανονισμό (ΕΕ) 2020/741 σχετικά με τις ελάχιστες απαιτήσεις για την επαναχρησιμοποίηση του νερού

Το ανακτημένο νερό μπορεί να χρησιμοποιηθεί για άρδευση στις εξής κατηγορίες καλλιεργειών, ανάλογα με την ποιότητα του νερού:

* Κατηγορία A: Όλες οι καλλιέργειες τροφίμων που καταναλώνονται ωμές και οι ριζοκαλλιέργειες που καταναλώνονται ωμές. Επιτρέπονται όλες οι μέθοδοι άρδευσης.
* Κατηγορία B: Καλλιέργειες τροφίμων που καταναλώνονται ωμές αλλά το βρώσιμο μέρος δεν έρχεται σε άμεση επαφή με το ανακτημένο νερό, καθώς και επεξεργασμένα τρόφιμα και μη βρώσιμες καλλιέργειες (π.χ. ζωοτροφές, ίνες, ενεργειακές καλλιέργειες). Επιτρέπονται όλες οι μέθοδοι άρδευσης.
* Κατηγορία C: Όμοιες με την Κατηγορία B, αλλά επιτρέπεται μόνο στάγδην άρδευση ή μέθοδος που αποφεύγει την επαφή με το βρώσιμο μέρος του φυτού.
* Κατηγορία D: Βιομηχανικές, ενεργειακές και σποροπαραγωγικές καλλιέργειες. Επιτρέπονται όλες οι μέθοδοι άρδευσης.

Οι ελάχιστες απαιτήσεις ποιότητας για κάθε κατηγορία αφορούν μικροβιολογικά κριτήρια όπως E. coli, Βιοχημική Απαίτηση Οξυγόνου (BOD_5), αιωρούμενα στερεά (TSS) και θολότητα, ενώ σε ορισμένες περιπτώσεις ελέγχονται και παθογόνοι μικροοργανισμοί όπως Legionella spp. και νηματώδεις

Το νερό από την επεξεργασία σας θα εμπίπτει στην κατηγορία A. Τα ίχνη φαρμακευτικών ουσιών στο παρών στάδιο απλά παρακολουθούνται και δεν εντάσσονται στις ελάχιστες απαιτήσεις ποιότητας. Η καινοτόμος μονάδα επεξεργασίας αναμένετε να αφαιρέσει το μεγαλύτερο ποσοστό από αυτές τις ενώσεις.

Με εκτίμηση

Αναστάσης Χρίστου

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