

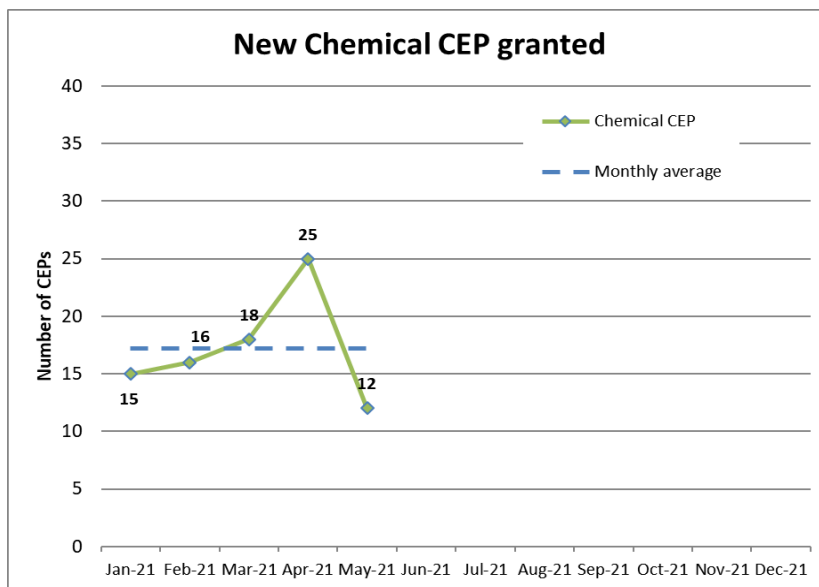
Certification of Substances Department

Strasbourg, June 2021

CERTIFICATION MONTHLY REPORT

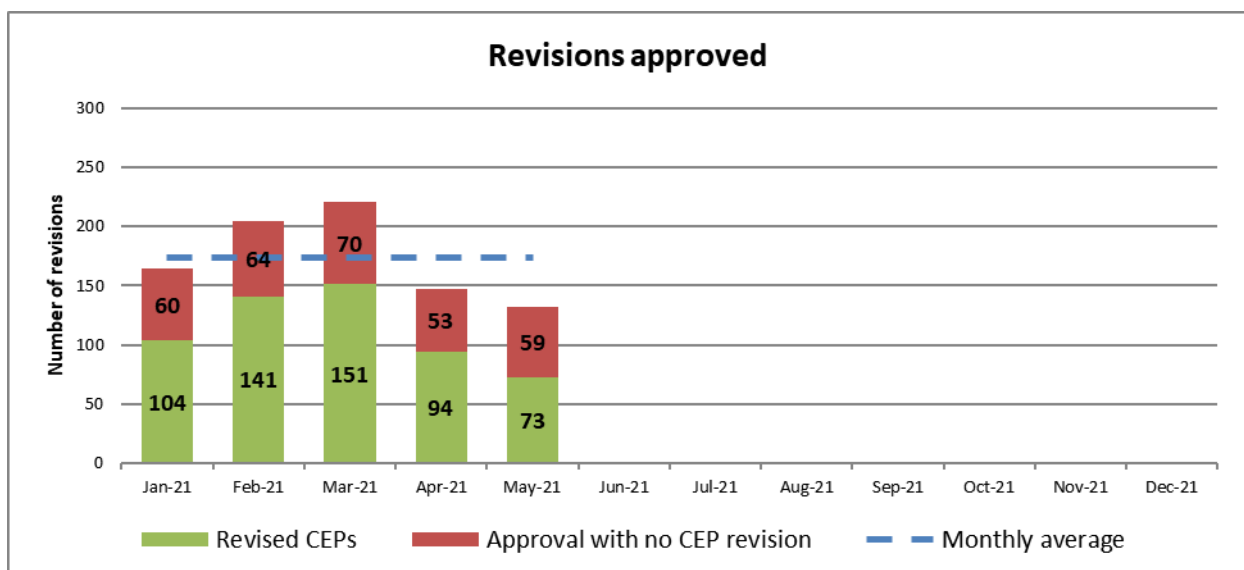
End of May 2021

New granted CEPs

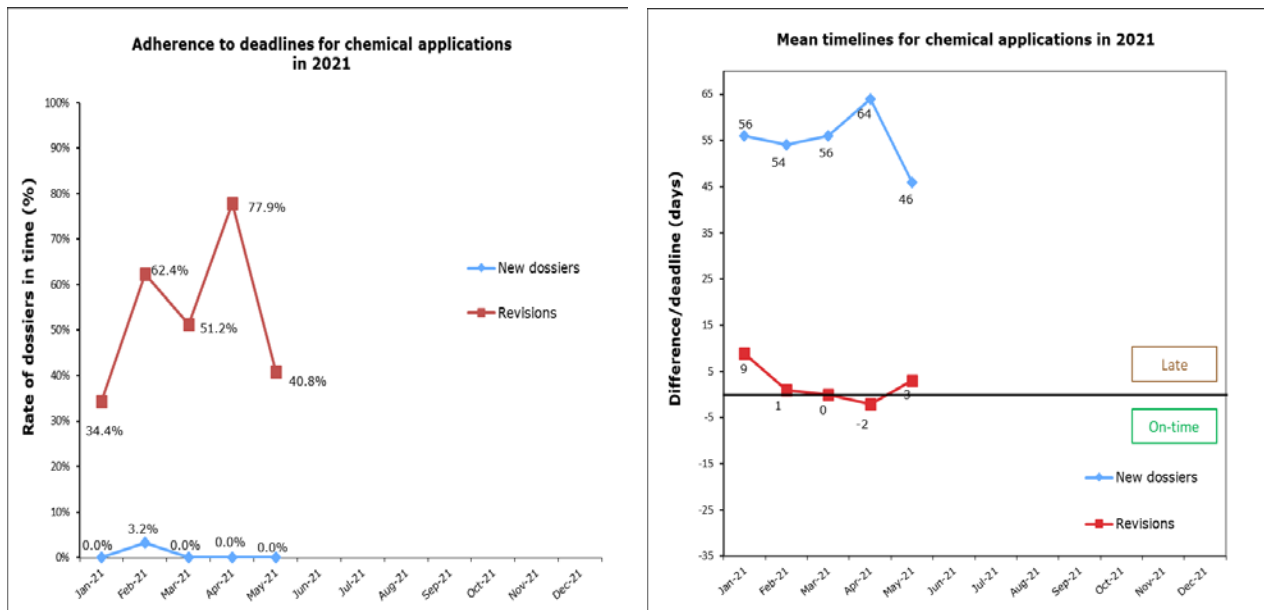


| | New CEPs granted (total 2021) |
|--------|----------------------------------|
| TSE | 4 |
| Herbal | 1 |

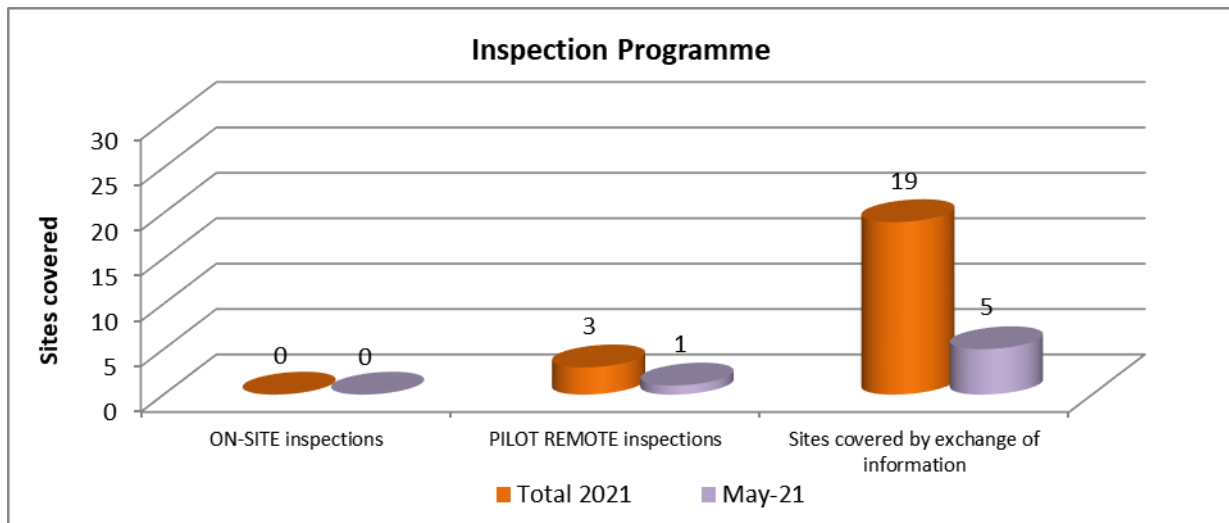
Revisions approved



Time for treatment (rate of dossiers treated in time for chemical applications)

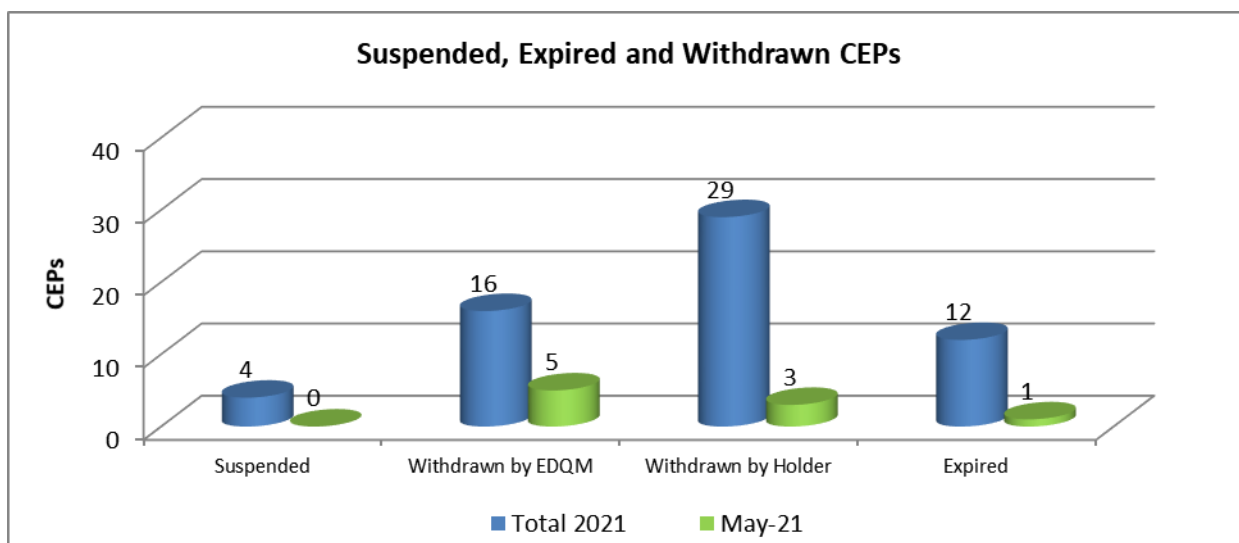


Inspections



The real-time remote inspection pilot phase is continuing with one more inspection in May 2021. The EDQM continues to work mainly with distant assessments and exchange of information with international partners.

Actions on CEPs



Information published on the EDQM Website (www.edqm.eu)

- Restoration of suspended CEPs:
 - CEP 2015-190 Ketorolac trometamol
 - Withdrawal of CEPs due to a failure to fulfil the requirements of the Certification procedure:
 - CEP 2010-116 Simvastatin
 - CEP 1995-039 Sulfadimidine
 - CEP 1997-008 Sulfadiazine
 - CEP 1997-009 Trimethoprim
 - CEP 1999-097 Sulfamethoxazole
 - 06/05/2021: EDQM Virtual Training Programme (28 June to 9 July)
 - 19/05/2021: Revision of the document "Implementation of policy on elemental impurities in the Certification Procedure".
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