## JUDGMENT OF THE COURT (First Chamber)

19 January 2023 (\*)

## CURIA - Documents (europa.eu)

(Reference for a preliminary ruling – Environment – Regulation (EC) No 1107/2009 – Placing of plant protection products on the market – Article 53(1) – Emergency situations in plant protection – Derogation – Scope – Seeds treated with plant protection products – Neonicotinoids – Active substances posing high risks to bees – Prohibition of the placing on the market and outside use of seeds treated with plant protection products containing those active substances – Implementing Regulation (EU) 2018/784 and Implementing Regulation (EU) 2018/785 – Non-applicability of the derogation – Protection of human and animal health and the environment – Precautionary principle)

In Case C-162/21,

REQUEST for a preliminary ruling under Article 267 TFEU from the Conseil d'État (Council of State, Belgium), made by decision of 16 February 2021, received at the Court on 11 March 2021, in the proceedings

With following conclusion:

Article 53(1) of 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

must be interpreted as not permitting a Member State to authorise the placing on the market of plant protection products for seed treatment, or the placing on the market and use of seeds treated with those products, where the placing on the market and use of seeds treated with those products have been expressly prohibited by an implementing regulation.

Interpretation and application of the ruling by Belgium

In anticipation of implementation by the Belgian "Conseil d'Etat"

- 1. The ruling is considered as a juridical, holistic interpretation of EU law. A literal interpretation would simply state that art. 53 of <u>Regulation 1107/2009</u> does not allow for the possibility to grant emergency authorisations for the sowing of treated seeds, whatever the status of the active substance, as it deals only with "the placing on the market of plant protection products, for limited and controlled use". The ruling is however restricted to active substances for which the placing on the market and the use of treated seeds have been expressly banned on EU level.
- 2. On the other hand, the ruling also excludes the treatment of the seeds, hence the use of plant protection products, without any further justification, although art. 53 foresees explicitly the possibility to grant emergency authorisations for the use of plant protection products, while seed treatment is a use of a plant protection product.

- 3. Apparently, the court considers that if the sowing of treated seeds is not permitted, that also the treatment itself should not be permitted, even if art 53 clearly gives a legal basis for a derogation for the use of the plant protection product itself. This ignores the possibility of treatment of seeds for export purposes only, hence not for sowing in the EU, which is no longer possible according to the ruling.
- 4. This also ignores the possibility of treatment of seeds that will only be sown under protection. The approval of the concerned active substances did not exclude the sowing under protection, which was hence still allowed. As the ruling refers in its point 43 to the 'conditions laid down by that (approval) regulation', by analogy it is understood that sowing under protection would not be excluded by the ruling.
- 5. Possibly, the court takes also into account the fact that the approvals of the concerned active substances were not only restricted for the sowing of the treated seeds but also for the treatment of the seeds itself, which is why the latter would need to be excluded as well. However, not every (future) restricted approval will necessarily be restricted in the same way.
- 6. Following this reasoning, the ruling has to be understood that art 53 can be invoked to grant emergency authorisations on the national level for the sowing of treated seeds, as long as the seed treatment and the sowing have not been excluded by the approvals for the active substances. Art 53 can also be invoked if restrictions apply that are not relevant for seed treatment and sowing of treated seeds. As mentioned in point 39 of the ruling, art. 53 could hence be invoked to grant emergency authorisations for seed treatment and sowing of treated seeds are not authorised at all (completely banned), or if only restrictions apply for other uses of the plant protection products than seed treatment.
- 7. As the concerned active substances imidacloprid, clothianidin and thiametoxam are no longer authorised at all, the approval regulations foreseeing the exclusion of seed treatment and sowing of treated seeds are no longer valid neither. The ruling states however that article 53 cannot apply if the placing on the market and the sowing of treated seeds have (ever) been prohibited, hence referring to the past, which is also the case once the approvals for the active substances are no longer valid. The ruling would hence also apply for emergency authorisations granted today for the concerned active substances. It could however be questioned whether the ruling would apply for active substances for which the approval in theory excludes sowing of treated seeds, completely or partly, without explicitly mentioning such exclusion of the sowing. E.g. an approval restricted to uses under protection does not mention the sowing but could be seen as excluding the sowing of treated seeds in open air.
- 8. The court makes in its ruling explicitly reference to the importance of protection of health and environment, and excludes the applicability of art. 53 if seed treatment and sowing are expressly excluded by the approval regulation of the active substance. If such exclusion is made expressly, this is only done after a risk assessment has demonstrated that the risk is unacceptable. Therefore, Belgium will apply this ruling taking into account the risk assessment that is on the basis of any such restriction for the active substance. If a restriction in the active substance approval is based on a risk assessment demonstrating an unacceptable risk due to the sowing of treated seeds, Belgium will no longer grant emergency authorisations for seed treatment and sowing of treated seeds. If the risk assessment would e.g. only be carried out for foliar uses, showing an unacceptable risk for use in open air, emergency authorisations for seed treatment and sowing of treated seeds would remain possible, even in open air. Also emergency authorisations for foliar uses in open air would remain possible, as the ruling is only dealing with treated seeds.
- 9. On the other hand, if an express prohibition of the treatment of seeds and the sowing of treated seeds would be made undone by means of a modification of the approval of the active

substance, e.g. after evaluation of submitted additional data showing that the risk is acceptable, an emergency authorisation would become possible again as well.

- 10. In any way, Belgium carries out a full risk assessment as for regular applications for authorisation of plant protection products, including the risks due to seed treatment and sowing of treated seeds, before granting emergency authorisations for any active substance. Such risk assessment is as much as possible taken into account in order to determine appropriate risk mitigation measures when granting an emergency authorisation. As for regular authorisations, this risk assessment is restricted to the exposure of operators and the quality of the plant protection product in case of an application for treatment of seeds for export purposes only.
- 11. The question raises whether the ruling could have wider consequences. The fact that the court accepts that art. 53 can be invoked for authorising the sowing of treated seeds, except when an express exclusion is made for the active substance, allows for the interpretation that sowing of seeds should be considered as the use of a plant protection product. Point 43 of the ruling states explicitly "that the legislature intended to permit Member States to authorise plant protection products, or, in the present case, seeds treated with such products, without complying with the conditions laid down by that regulation (...)". In points 36 and 37, reference is made to article 28 of Regulation 1107/2009 which states in point 1 that "A plant protection product shall not be placed on the market or used unless it has been authorised in the Member State concerned in accordance with this Regulation." Hence, if art. 53 is considered to allow for the possibility of granting emergency authorisations for the sowing of treated seeds while dealing only with 'the placing on the market of plant protection products, for limited and controlled use' and 'by way of derogation of art. 28' which deals itself also only with the placing on the market and the use of plant protection products, also the sowing of treated seeds can and needs to be authorised by the member states. Application of this principle would on the other hand hamper the free movement of treated seeds within the EU. Hence, a legal basis would need to be created in order to implement such principle. Hence, for the time being, Belgium will only see this as a confirmation that the sowing of treated seeds needs to be considered when granting authorisations for placing on the market of plant protection products for seed treatment.
- 12. The ruling excludes only the placing on the market and the sowing of treated seeds when these are expressly prohibited. Such a prohibition is considered equal to a restriction of the use of the active substance, when the approval excludes the placing on the market and the sowing of the treated seeds.
- 13. Only the Conseil d'Etat can make annulment of emergency authorisations that were granted before the date of the ruling and that would be considered in conflict with it.
- 14. Imidacloprid, thiamethoxam, clothianidin, metalaxyl-M and thiram are the only active substances for which an express prohibition of the treatment of seeds and the sowing of treated seeds is in place today. Restrictions for other active substances like indoxacarb exclude the use in open air, without an express prohibition of the treatment of seeds and the sowing of treated seeds and without a risk assessment showing that such use would be unacceptable.
- 15. In concrete, this leads to the following for Belgium:
  - a. As from the date of the ruling, no emergency authorisation will be granted in Belgium for the treatment of seeds and the sowing of treated seeds with imidacloprid, thiamethoxam, clothianidin, metalaxyl-M and thiram, not even for seeds for export purposes only.

- b. The granted Belgian emergency authorisations for treatment of seeds for export purposes only with imidacloprid or thiamethoxam remain valid as long as the Conseil d'Etat has not taken the decision to annul them.
- c. Emergency authorisations can be granted by Belgium for any use of indoxacarb or any other active substance for which the use restricted, as long as the treatment of seeds and the sowing of treated seeds is not expressly prohibited by the approval of the active substance.