

## **Background information**

- 1.1 Any new pesticide on the market in Northern Ireland must obtain authorisation for the product under the terms of EC Regulation 1107/2009, Plant Protection Products.
- 1.2 Before a company applies to put a pesticide on the market it must gain approval for the active substance. Active substances such as glyphosate are the essential ingredients in the pesticide that enable the product to do its job.
- 1.3 The process for deciding whether a new active substance can be approved for use in plant protection products in the European Union (EU), involves all Member States, the European Food Safety Authority (EFSA) and the European Commission.
- 1.4 Pesticide applications from industry pass along a chain formed of these three parties – with each one carrying out specific tasks.
- 1.5 When a company submits an application for approval of an active substance to a Member State, the application contains supporting scientific information and studies. This application can be for a new active substance or for the renewal or amendment of a previously approved one.
- 1.6 In consultation with other Member States, EFSA carries out a peer review of the assessment report and sends its conclusions to the European Commission. These may include options for risk management measures.
- 1.7 On the basis of EFSA's review, The European Commission makes a proposal on whether or not to approve the application. A special committee of Member State representatives then votes on this proposal.
- 1.8 A new active substance is usually approved for 10 years, while an application for renewal of approval can be granted for up to 15 years.
- 1.9 Glyphosate is the most widely used herbicide in the world. A broad spectrum herbicide, its uses include weed control in agriculture, vegetation control in non-agricultural areas, and harvesting aid as crop desiccant.

- 2.0 Since glyphosate was introduced in 1974, all regulatory assessments have established that glyphosate has low hazard potential to mammals, however, the International Agency for Research on Cancer (IARC) concluded in March 2015 that it is probably carcinogenic.
- 2.1 Consequently, the IARC conclusion triggered a reconsideration of the evidence on carcinogenicity in the EU evaluation, and more recently by the Joint FAO/WHO Meeting on Pesticide Residues.
- 2.2 The European Union renewal process was the first comprehensive regulatory assessment of glyphosate conducted after the IARC evaluation.
- 2.3 In November 2015, the European Food Safety Authority (EFSA) found it 'unlikely to pose a carcinogenic hazard to humans' based on a 'large body of evidence', including 'key studies not considered by IARC' that remain unpublished.
- 2.4 In 2016 the Joint FAO/WHO Meeting on Pesticide Residues concluded that glyphosate is not carcinogenic in rats but could not exclude the possibility that it is carcinogenic in mice at very high doses. This information was used in the risk assessment concluding that glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet.
- 2.5 Following these divergences, the European Chemicals Agency (ECHA) was asked to assess the hazard properties of the substance before taking a decision on its potential renewal at EU level.
- 2.6 It concluded in March 2017, on the basis of the evidence used by EFSA, that glyphosate did not class as a carcinogen.
- 2.7 In July 2017, the Commission proposed to renew the approval of glyphosate for 10 years. In the face of opposition by some Member States, the Commission proposed, in early November 2017, a five-year renewal. On 12 December 2017 the Commission adopted the act to renew the approval of glyphosate for 5 years.