



สหภาพยุโรป

เรื่อง อาหารใหม่

(REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001)

รายละเอียด	:	ข้อกำหนดสำหรับอาหารใหม่ หรือ Novel Food
กลุ่มอาหาร	:	อาหารใหม่ (Novel food)
ลำดับชั้นกฎหมาย	:	ระเบียบ
หัวข้อสำคัญ	:	-
วันที่ออกประกาศ	:	25 พฤศจิกายน 2558
วันที่บังคับใช้	:	15 ธันวาคม 2558
วันที่ปรับปรุงล่าสุด	:	18 ธันวาคม 2555



สหภาพยุโรป เรื่อง อาหารใหม่

(REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001)

บังคับใช้ วันที่ 15 เดือน ธันวาคม พ.ศ. 2558

รายละเอียดโดยสรุป

สหภาพยุโรปได้ออกระเบียบควบคุมสำหรับอาหารที่ผลิตขึ้นมาใหม่ หรือ Novel foods ภายใต้ระเบียบ 2 ฉบับ ได้แก่

- 1) **Regulation (EC) No 258/97** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 1991 concerning novel foods and novel food ingredients และ
- 2) **Regulation (EC) No 1852/2001** of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97

โดยมีผลบังคับใช้มาตั้งแต่วันที่ 15 พฤษภาคม 2540 ว่าด้วยการอนุญาตวางจำหน่ายอาหารประเภท novel foods และอาหารที่มีส่วนผสมของ novel foods ในตลาดสหภาพยุโรป ต่อมาปี 2545 ถึง 2550 คณะกรรมาธิการยุโรปได้ทำการหารือกับสาธารณชน ผู้มีส่วนได้ส่วนเสีย และสมาชิกสหภาพยุโรปเพื่อรับทราบความเห็นต่างๆ เกี่ยวกับการปรับปรุงกระบวนการอนุญาตวางจำหน่ายอาหาร novel foods ในสหภาพฯ จนกระทั่งเมื่อวันที่ 14 มกราคม 2551 คณะกรรมาธิการยุโรปได้ออกแถลงข่าวว่าด้วยข้อเสนอที่คณะกรรมาธิการฯ ประสงค์จะนำมาบังคับใช้เพื่อปรับปรุงกฎระเบียบอาหาร novel foods ที่มีมาแต่เดิม

ผลจากการหารือทำให้เห็นความจำเป็นที่จะต้องปรับปรุงกฎระเบียบเรื่อง novel foods ให้สอดคล้องกับนวัตกรรมใหม่ๆ ที่เกิดขึ้น โดยมีจุดมุ่งหมายเพื่อเพิ่มประสิทธิภาพของขั้นตอนการอนุญาต (authorization procedure) ให้อาหารที่มีนวัตกรรมใหม่ (innovative) และมีความปลอดภัย (safe) ได้รับอนุญาตให้วางจำหน่ายในตลาดสหภาพฯ ได้เร็วขึ้น และเพื่อลดข้อกีดกันทางการค้าอย่างไม่จำเป็น ในขณะที่ยังคงให้ความสำคัญกับการควบคุมความปลอดภัยของอาหาร นอกจากนี้ จำเป็นที่จะต้องปรับปรุงกฎระเบียบเพื่อแยกอาหารที่มีการดัดแปรพันธุกรรม (GMOs) ออกจากกฎระเบียบ novel foods เพราะ GMOs เป็นอาหารที่มี

กฎหมายเฉพาะควบคุมอยู่แยกต่างหากตั้งแต่ปี 2546 แล้ว ซึ่งการหาร้อยยังรวมถึงรายละเอียดของการติดฉลาก novel foods ต้องเป็นไปตามระเบียบการแสดงข้อมูลสินค้าอาหารบนฉลากใน Regulation 1169/2011 และการอ้างอิงคุณค่าทางอาหารตามระเบียบ Regulation 1924/2006 เช่นเดียวกับอาหารทั่วไป

ต่อมาในปี 2555 สหภาพยุโรปยังได้ออกข้อเสนอ Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on novel foods เพื่อรวบรวมข้อมูลสำหรับปรับแก้ไขข้อกำหนดอาหารใหม่ให้เหมาะสมมากยิ่งขึ้นสำหรับขอบเขต การประเมินความเสี่ยงและความปลอดภัย ขั้นตอนการขออนุญาต และการวางจำหน่ายในตลาดสหภาพฯ โดยประกาศเป็นระเบียบฉบับใหม่ คือ Regulation 2015/2283 ฉบับนี้ซึ่งมีรายละเอียดสรุปได้ดังนี้

1. อาหารใหม่ หรือ Novel food แต่**ไม่รวมถึง**อาหารตามข้อกำหนดต่อไปนี้

- 1) อาหารดัดแปรพันธุกรรม (Genetically modified foods) ตาม Regulation 1829/2003
- 2) อาหารที่อยู่ภายใต้ขอบเขตของระเบียบ ต่อไปนี้
 - ก) Food enzyme ตามขอบเขตใน Regulation 1332/2008
 - ข) Food additives ตามขอบเขตใน Regulation 1333/2008
 - ค) Food flavouring ตามขอบเขตใน Regulation 1334/2008
 - ง) สารสกัดหรือตัวทำละลายที่ใช้ในการเตรียมอาหารหรือส่วนผสมตามขอบเขตใน Directive 2009/32/EC

2. คำนิยาม

- 1) “อาหารใหม่” (Novel food) หมายถึง อาหารที่ไม่มีการนำไปใช้เพื่อการบริโภคของมนุษย์ภายในสหภาพฯ ก่อนวันที่ 15 พฤษภาคม 2540 โดยไม่คำนึงวันที่ได้เข้ามาในประเทศสมาชิกสหภาพฯ โดยอย่างน้อยต้องเป็นอาหารตามข้อกำหนดต่อไปนี้

 - (1) อาหารชนิดใหม่หรือมีโครงสร้างทางโมเลกุลที่แตกต่างจากอาหารเดิมที่มีอยู่ในสหภาพก่อนวันที่ 15 พฤษภาคม 2540
 - (2) อาหารที่มีส่วนประกอบหรือแยกออกหรือผลิตจากจุลินทรีย์ (microorganism) รา (fungi) และสาหร่าย (algae)
 - (3) อาหารที่มีส่วนประกอบหรือแยกออกหรือผลิตจากวัสดุหรือมีต้นกำเนิดจากแร่ธาตุ (material of mineral origin)
 - (4) อาหารที่มีส่วนประกอบหรือแยกออกหรือผลิตจากพืชหรือส่วนต่างๆ ของพืช ยกเว้นที่มีประวัติว่ามีความปลอดภัยที่ใช้เป็นอาหารภายในสหภาพฯ โดยส่วนประกอบหรือการผลิตนั้นมาจากพืชชนิดต่างๆ ที่
 - (ก) มีการแพร่พันธุ์มาตั้งแต่โบราณหรือใช้ผลิตเป็นอาหารในสหภาพก่อน 15 พฤษภาคม 2540

- (ข) ไม่ได้มีมาแต่โบราณแต่ใช้ผลิตเป็นอาหารในสหภาพฯ ก่อน 15 พฤษภาคม 2540 โดยไม่มีการเปลี่ยนแปลงส่วนประกอบหรือโครงสร้างของอาหารในด้านคุณค่าทางโภชนาการ, เมตาบอลิซึม หรือระดับของสารที่ไม่สามารถระบุได้
- (5) อาหารที่มีส่วนประกอบของหรือแยกออกจากหรือผลิตจากสัตว์หรือส่วนต่างๆ ของสัตว์ยกเว้นสัตว์ที่ผสมพันธุ์มาแต่ครั้งโบราณซึ่งมีการผลิตเป็นอาหารในสหภาพฯ ก่อนวันที่ 15 พฤษภาคม 2540 และอาหารจากสัตว์นั้นมีประวัติถึงความปลอดภัยอาหารในสหภาพฯ
- (6) อาหารที่มีส่วนประกอบของหรือแยกออกจากหรือผลิตจากการเพาะเลี้ยงเนื้อเยื่อที่ได้จากสัตว์ พืช จุลินทรีย์ รา หรือสาหร่าย
- (7) อาหารที่ได้จากกระบวนการผลิตที่ไม่เคยถูกใช้ผลิตมาก่อนวันที่ 15 พฤษภาคม 2540 ซึ่งอาจมีการเปลี่ยนแปลงโครงสร้างหรือส่วนประกอบของอาหารในด้านคุณค่าทางโภชนาการ, เมตาบอลิซึม หรือระดับของสารที่ไม่สามารถระบุได้
- (8) อาหารที่ได้กระบวนการวิศวกรรมทางวิศวกรรม
- (9) วิตามิน, แร่ธาตุ และสารอื่นๆ ที่ใช้ตาม Directive 2002/46/EC, Regulation (EC) 1925/2006 หรือ Regulation 609/2013 โดยที่
- (ก) กระบวนการผลิตไม่ใช้การผลิตอาหารภายในสหภาพฯ ก่อนวันที่ 15 พฤษภาคม 2540 ตามที่ระบุไว้ในข้อ (5) หรือ
- (ข) มีส่วนประกอบที่ได้จากกระบวนการทางวิศวกรรม
- (10) อาหารที่จำหน่ายเป็นผลิตภัณฑ์เสริมอาหารภายในสหภาพฯ ก่อนวันที่ 15 พฤษภาคม 2540 หรือใช้เป็นอาหารอื่นจากผลิตภัณฑ์เสริมอาหารตามข้อ (a) ในมาตรา 2 ของ Directive 2002/46/EC
- 2) “ประวัติด้านความปลอดภัยอาหารในประเทศที่สาม” (history of safe food use in a third country) หมายถึงความปลอดภัยของอาหารในกรณีที่ต้องการยืนยันถึงข้อมูลส่วนประกอบและประวัติการใช้อย่างน้อย 25 ปี เมื่อใช้บริโภคเป็นอาหารแก่ประชากรอย่างน้อย 1/3 ของประเทศ
- 3) “อาหารดั้งเดิมจากประเทศที่สาม” (traditional food from a third country) หมายถึงอาหารใหม่ตามข้อ 1) (1), (3), (7), (9), และ (10) ซึ่งมีกระบวนการผลิตขึ้นต้นตาม Regulation 178/2002 ซึ่งมีประวัติความปลอดภัยในการใช้เป็นอาหารในประเทศที่สาม
- 4) “ผู้ขออนุญาต” (the applicant) หมายถึง สมาชิกสหภาพฯ, ประเทศที่สาม หรือผู้สนใจซึ่งเป็นตัวแทนติดต่อกับคณะกรรมการเพื่อขอพิจารณาตามขั้นตอนในมาตรา 10 หรือ 16 หรือตามรายละเอียดเอกสารในมาตรา 14

- 5) “ใช้ได้ตามกฎหมาย” (valid) ในเอกสารคำขอหรือประกาศหมายถึง ระยะเวลาขอบเขตของระเบียบและองค์ประกอบของข้อมูลการประเมินความเสี่ยงและขั้นตอนที่ได้รับอนุญาต
 - 6) “วัสดุวิศวกรรมนาโน” (engineered nanomaterial) หมายถึง วัสดุที่ตั้งใจผลิตให้มีเส้นผ่านศูนย์กลาง 100 nm หรือต่ำกว่า ซึ่งประกอบด้วยฟิซันต่างๆ ไม่ว่าจะ เป็นภายในหรือพื้นผิวหนึ่งหรือหลายมิติที่ระดับ 100 nm หรือต่ำกว่า รวมถึงโครงสร้าง การรวมตัวเป็นกลุ่มก้อน ซึ่งอาจทำให้มีขนาดใหญ่กว่า 100 nm แต่ยังคงมีคุณสมบัติเช่นเดียวกันนาโนสเกล
คุณสมบัติในระดับนาโนสเกล รวมถึง
 - (ก) พื้นผิวเฉพาะซึ่งมีขนาดใหญ่ของวัสดุ และ/หรือ
 - (ข) คุณสมบัติทางเคมี-กายภาพเฉพาะซึ่งต่างจากวัสดุชนิด non-nanoform
3. ขั้นตอนการพิจารณาสถานะของอาหารใหม่
- 1) หน่วยธุรกิจสามารถยื่นขอพิจารณาอาหารที่จำหน่ายในสหภาพได้ตามขอบเขตของระเบียบฉบับนี้
 - 2) หากพบว่ามีข้อสงสัยเรื่องสถานที่หรือการจำหน่ายภายในสหภาพผู้ประกอบการสามารถขอคำแนะนำจากสมาชิกสหภาพฯ ในที่แรกที่ยื่นขออาหารใหม่ ซึ่งอาจจำเป็นต้องมีข้อมูลให้พิจารณาว่าเป็นอาหารตามขอบเขตที่ระบุในระเบียบฉบับนี้หรือไม่
4. ข้อกำหนดสำหรับการจำหน่ายอาหารใหม่ในตลาดภายในสหภาพฯ
- 1) บัญชีรายชื่อของสหภาพฯ (Union list) สำหรับอาหารใหม่ ซึ่งคณะกรรมการจะปรับปรุงบัญชีรายชื่ออาหารใหม่ที่ได้รับอนุญาตจำหน่ายในสหภาพฯ และข้อกำหนดในการแสดงฉลากด้วย
 - 2) ข้อกำหนดทั่วไปสำหรับอาหารใหม่ในบัญชีรายชื่อ ไม่ว่าจะ เป็นอาหารหรือไม่ใช่อาหารต้องอยู่บนพื้นฐานข้อมูลทางวิทยาศาสตร์ที่เหมาะสม ปราศจากความเสี่ยงอันตรายต่อสุขภาพของมนุษย์ ไม่ทำให้ผู้บริโภคเข้าใจผิดโดยเฉพาะอย่างยิ่งการใช้เพื่อทดแทนอาหารอื่นๆ หรือเปลี่ยนแปลงคุณค่าทางโภชนาการ หากต้องการใช้เพื่อทดแทนอาหารบางชนิดต้องไม่มีความแตกต่างจากอาหารเดิมเมื่อบริโภคปกติรวมทั้งไม่ให้สารอาหารที่ไร้ประโยชน์สำหรับผู้บริโภค
 - 3) ตั้งแต่วันที่ 1 มกราคม 2561 คณะกรรมการจะประกาศบัญชีรายชื่ออาหารใหม่ที่ผ่านมาการอนุญาตเป็นที่เรียบร้อยแล้ว
 - 4) รายละเอียดและการปรับปรุงบัญชีรายชื่อจะกระทำเมื่อ
 - (ก) มีอาหารใหม่เพิ่มเติม
 - (ข) มีการถอนรายชื่อ

- (ค) มีการถอดถอน เพิ่มเติม หรือเปลี่ยนแปลงคุณสมบัติคุณลักษณะของการใช้, เพิ่มข้อกำหนดฉลาก หรือต้องประเมินการตรวจติดตามในตลาดที่เกี่ยวข้องกับอาหารใหม่ในบัญชีรายชื่อ
5. ขั้นตอนการขออนุญาตวางจำหน่ายอาหารใหม่ที่อยู่ในสหภาพและการปรับปรุงบัญชีรายชื่อ
- 1) สำหรับผู้ที่ต้องการขออนุญาตจำหน่ายอาหารใหม่ในตลาดสหภาพและต้องการแก้ไขรายชื่อใน Union list จะส่งเอกสารข้อมูลในคณะกรรมการพิจารณา ดังนี้
- (ก) ชื่อและที่อยู่ผู้ยื่นขอ
- (ข) ชื่อและรายละเอียดของอาหารใหม่
- (ค) รายละเอียดกระบวนการผลิต
- (ง) รายละเอียดส่วนประกอบ
- (จ) ข้อมูลทางวิทยาศาสตร์ที่แสดงให้เห็นว่าอาหารใหม่ไม่เป็นสาเหตุของความเสี่ยงอันตรายต่อสุขภาพของมนุษย์
- (ฉ) ข้อมูลวิธีวิเคราะห์ทดสอบ
- (ช) เอกสารข้อเสนอที่เกี่ยวข้องกับการนำไปใช้และข้อกำหนดด้านฉลากซึ่งไม่ทำให้เกิดความเข้าใจผิดของผู้บริโภค
- 2) เอกสารที่สำนักความปลอดภัยอาหารแห่งยุโรป (European Food Safety Authority: EFSA) ร้องขอเพื่อให้ข้อคิดเห็นต่อผลกระทบต่อสุขภาพของมนุษย์
- 3) ในกรณีที่ผลทดสอบมีการใช้วัสดุทางวิศวกรรมนาโน ต้องมีเอกสารทางเทคนิคและรายละเอียดของวัสดุที่ใช้ด้วย
6. อาหารใหม่ที่น่าเข้าจากประเทศที่สาม กรณีที่ผู้นำเข้าอาหารใหม่ที่เป็นอาหารดั้งเดิมจากประเทศที่สามต้องยื่นขออนุญาตเพื่อวางจำหน่ายในสหภาพฯ โดยมีเอกสารประกอบด้วย
- 1) ชื่อและที่อยู่ของผู้ยื่นขอ
- 2) ชื่อและรายละเอียดของอาหาร
- 3) รายละเอียดของส่วนประกอบอาหาร
- 4) ประเทศหรือกลุ่มประเทศแหล่งกำเนิดของอาหาร
- 5) เอกสารข้อมูลประวัติความปลอดภัยของอาหารในประเทศที่สาม
- โดยขั้นตอนการยื่นขออนุญาตดำเนินการเช่นเดียวกับอาหารใหม่ในสหภาพฯ
7. หลังการยื่นขออนุญาตเอกสารอาณัติปฏิบัติคำขอภายใน 3 สัปดาห์เนื่องจากมีข้อสงสัยในข้อมูลซึ่งผู้ยื่นขออนุญาตสามารถส่งเอกสารหลักฐานเพิ่มเติมได้เพื่อประกอบการพิจารณาอีกครั้ง

8. หลังได้รับอนุญาตให้วางจำหน่ายอาหารใหม่ สหภาพฯ อาจมีข้อคิดเห็นหรือข้อกำหนดด้านความปลอดภัยอาหารในระบบ post-market แล้วแต่กรณีได้
9. อาจมีข้อกำหนดเพิ่มเติมในอนาคต เช่น ข้อมูลทางวิทยาศาสตร์ ข้อมูลด้านเทคนิค ข้อห้ามหรือข้อจำกัดจากประเทศแหล่งกำเนิดอาหาร ต้องส่งรายละเอียดข้อมูลในคณะกรรมการพิจารณาซ้ำ เพราะอาจมีการแก้ไขใบอนุญาตได้
10. การแก้ไขรายละเอียดตาม Regulation 1169/2011 เป็นการเพิ่มคำนิยามของ “engineered nanomaterials” ตามความหมายในระเบียบนี้
11. ยกเลิกระเบียบเดิม 2 ฉบับ ได้แก่
 - 1) Regulation 258/97
 - 2) Regulation 1852/2001ตั้งแต่วันที่ 1 มกราคม 2561 เป็นต้นไป

ระยะเวลาเปลี่ยนผ่าน

ระเบียบนี้จะมีผลบังคับใช้ตั้งแต่วันที่ 1 มกราคม 2561

ประกาศฉบับเต็ม

ระเบียบ (REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 สามารถดูรายละเอียดได้จากเอกสารแนบหรือเว็บไซต์ต่อไปนี้

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2283&from=EN>

ข้อมูลเพิ่มเติม:

กฎ ระเบียบ และมาตรฐานสินค้าอาหารไทยและประเทศคู่ค้า สามารถดูรายละเอียดเพิ่มเติมได้จากฐานข้อมูลกฎหมายมาตรฐานอาหาร ภายในเว็บไซต์ศูนย์อัจฉริยะเพื่ออุตสาหกรรมอาหาร เมนู Law & Safety (<http://fic.nfi.or.th>)

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 25 November 2015****on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001****(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests. Differences between national laws concerning the safety assessment and authorisation of novel foods may hinder the free movement of such food, thereby creating legal uncertainty and unfair conditions of competition.
- (2) A high level of protection of human health and of consumers' interests and the effective functioning of the internal market needs to be assured in the pursuit of Union food policies, whilst ensuring transparency. A high level of protection and improvement of the quality of the environment are among the objectives of the Union as established in the Treaty on European Union (TEU). It is important that all relevant Union legislation, including this Regulation, take those objectives into account.
- (3) Union legislation applicable to food is also applicable to novel foods placed on the market within the Union, including novel foods imported from third countries.
- (4) The Union's rules on novel foods were established by Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽³⁾ and by Commission Regulation (EC) No 1852/2001 ⁽⁴⁾. Those rules need to be updated

⁽¹⁾ OJ C 311, 12.9.2014, p. 73.

⁽²⁾ Position of the European Parliament of 28 October 2015 (not yet published in the Official Journal) and decision of the Council of 16 November 2015.

⁽³⁾ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

⁽⁴⁾ Commission Regulation (EC) No 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97 (OJ L 253, 21.9.2001, p. 17).

to simplify the current authorisation procedures and to take account of recent developments in Union law and technological progress. Regulations (EC) No 258/97 and (EC) No 1852/2001 should be repealed and replaced by this Regulation.

- (5) Food intended to be used for technological purposes and genetically modified food which is already covered by other Union acts should not fall within the scope of this Regulation. Therefore, genetically modified food falling within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council ⁽¹⁾, food enzymes falling within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council ⁽²⁾, food used solely as additives falling within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council ⁽³⁾, food flavourings falling within the scope of Regulation (EC) No 1334/2008 of the European Parliament and of the Council ⁽⁴⁾ and extraction solvents falling within the scope of Directive 2009/32/EC of the European Parliament and of the Council ⁽⁵⁾ should be excluded from the scope of this Regulation.
- (6) The existing definition of novel food in Regulation (EC) No 258/97 should be clarified and updated with a reference to the general definition of food provided for in Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽⁶⁾.
- (7) In order to ensure continuity with the rules laid down in Regulation (EC) No 258/97, one of the criteria for food to be considered a novel food should continue to be the absence of use for human consumption to a significant degree within the Union before the date of entry into force of that Regulation, namely 15 May 1997. Use within the Union should also refer to a use in the Member States irrespective of the dates of their accession.
- (8) The scope of this Regulation should, in principle, remain the same as the scope of Regulation (EC) No 258/97. However, on the basis of scientific and technological developments that have occurred since 1997, it is appropriate to review, clarify and update the categories of food which constitute novel foods. Those categories should cover whole insects and their parts. There should be, inter alia, categories for food with a new or intentionally modified molecular structure, as well as for food from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae, for food from microorganisms, fungi or algae and for food from material of mineral origin. There should also be a category covering food from plants obtained by non-traditional propagating practices where those practices give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances. The definition of novel food may also cover food consisting of certain micelles or liposomes.
- (9) Emerging technologies in food production processes may have an impact on food and thereby on food safety. Therefore, this Regulation should further specify that a food should be considered a novel food where it results from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food affecting its nutritional value, metabolism or level of undesirable substances.
- (10) To ensure a high level of protection of human health and consumers' interests, food consisting of engineered nanomaterials should also be considered a novel food under this Regulation. The term 'engineered nanomaterial'

⁽¹⁾ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

⁽²⁾ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p. 7).

⁽³⁾ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

⁽⁴⁾ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).

⁽⁵⁾ Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3).

⁽⁶⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

is currently defined in Regulation (EU) No 1169/2011 of the European Parliament and of the Council ⁽¹⁾. For consistency and coherence purposes, it is important to ensure a single definition of engineered nanomaterial in the area of food law. The appropriate legislative framework for including such a definition is this Regulation. Accordingly, the definition of engineered nanomaterial, along with the related conferral of delegated powers to the Commission, should be deleted from Regulation (EU) No 1169/2011 and replaced by a reference to the definition set out in this Regulation. Furthermore, this Regulation should provide that the Commission should, by means of delegated acts, adjust and adapt the definition of engineered nanomaterial set out in this Regulation to technical and scientific progress or to definitions agreed at international level.

- (11) Vitamins, minerals and other substances intended to be used in food supplements in accordance with Directive 2002/46/EC of the European Parliament and of the Council ⁽²⁾ and Regulation (EC) No 1925/2006 of the European Parliament and of the Council ⁽³⁾ or in infant formula and follow-on formulae, processed cereal-based food and baby food for infants and young children, food for special medical purposes, and total diet replacement for weight control in accordance with Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽⁴⁾, should also be assessed in accordance with the rules laid down in this Regulation when they fall within the definition of novel food set out therein.
- (12) Where vitamins, minerals or other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013 result from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances, or where those vitamins, minerals or other substances contain or consist of engineered nanomaterials, they should also be considered novel foods under this Regulation and should be re-assessed first in accordance with this Regulation and subsequently in accordance with the relevant specific legislation.
- (13) A food used before 15 May 1997 exclusively as, or in, a food supplement, as defined in Directive 2002/46/EC, should be permitted to be placed on the market within the Union after that date for the same use, as it should not be considered to be a novel food for the purposes of this Regulation. However, that use as, or in, a food supplement should not be taken into account for the assessment of whether the food was used for human consumption to a significant degree within the Union before 15 May 1997. Therefore, uses of the food concerned other than as, or in, a food supplement should be subject to this Regulation.
- (14) Food from animal clones has been regulated under Regulation (EC) No 258/97. It is crucial that no legal ambiguity should emerge as regards the placing on the market of food from animal clones during the transitional period after the end of the application of Regulation (EC) No 258/97. Therefore, until specific legislation on food from animal clones enters into force, food from animal clones should fall under the scope of this Regulation as food from animals obtained by non-traditional breeding practices and should be appropriately labelled for the final consumer in accordance with the Union legislation in force.
- (15) The placing on the market within the Union of traditional foods from third countries should be facilitated where the history of safe food use in a third country has been demonstrated. Those foods should have been consumed in at least one third country for at least 25 years as a part of the customary diet of a significant number of people. The history of safe food use should not include non-food uses or uses not related to normal diets.

⁽¹⁾ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

⁽²⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

⁽³⁾ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

⁽⁴⁾ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

- (16) Foods from third countries which are regarded as novel foods in the Union should only be considered as traditional foods from third countries when they are derived from primary production as defined in Regulation (EC) No 178/2002, regardless of whether or not they are processed or unprocessed foods.
- (17) Food produced exclusively from food ingredients that do not fall within the scope of this Regulation, in particular by changing the ingredients of the food or their amount, should not be considered to be a novel food. However, modifications to a food ingredient that has not yet been used for human consumption to a significant degree within the Union, should fall within the scope of this Regulation.
- (18) Directive 2001/83/EC of the European Parliament and of the Council ⁽¹⁾ applies in cases where a product, taking into account all its characteristics, may fall both within the definition of 'medicinal product' as laid down in that Directive and within the definition of a product covered by this Regulation. In that respect, where a Member State establishes in accordance with Directive 2001/83/EC that a product is a medicinal product, it may restrict the placing on the market of that product in accordance with Union law. Moreover, medicinal products are excluded from the definition of food as laid down in Regulation (EC) No 178/2002 and should therefore not fall within the scope of this Regulation.
- (19) The determination of whether a food was used for human consumption to a significant degree within the Union before 15 May 1997 should be based on information submitted by food business operators and, where appropriate, supported by other information available in Member States. Food business operators should consult Member States if they are unsure of the status of the food which they intend to place on the market. Where there is no information on human consumption before 15 May 1997 or the information available is insufficient, a simple and transparent procedure, involving the Commission, the Member States and food business operators, should be established for collecting such information.
- (20) Novel foods should be authorised and used only if they fulfil the criteria laid down in this Regulation. Novel foods should be safe and if their safety cannot be assessed and scientific uncertainty persists, the precautionary principle may be applied. Their use should not mislead the consumer. Therefore, where a novel food is intended to replace another food, it should not differ from that food in a way that would be nutritionally less advantageous for the consumer.
- (21) Novel foods should not be placed on the market or used in food for human consumption unless they are included in a Union list of novel foods authorised to be placed on the market within the Union ('the Union list'). Therefore, it is appropriate to establish, by means of an implementing act, the Union list by including in that list the novel foods already authorised or notified in accordance with Regulation (EC) No 258/97, including any existing authorisation conditions. That list should be transparent and easily accessible.
- (22) It is appropriate to authorise a novel food by updating the Union list subject to the criteria and procedures laid down in this Regulation. A procedure that is efficient, time-limited and transparent should be put in place. As regards traditional foods from third countries having a history of safe food use, the applicants should be able to opt for a faster and simplified procedure to update the Union list if no duly reasoned safety objections are expressed.
- (23) Criteria for the assessment of the safety risks arising from novel foods should also be clearly defined and laid down. In order to ensure the harmonised scientific assessment of novel foods, such assessments should be carried out by the European Food Safety Authority ('the Authority'). Under the procedure for authorising a novel food and updating the Union list, the Authority should be requested to give its opinion if the update is liable to have an effect on human health. In its opinion, the Authority should assess, inter alia, all the characteristics of the novel food that may pose a safety risk to human health and consider possible effects on vulnerable groups of the population. In particular, the Authority should verify that, where a novel food consists of engineered nanomaterials, the most up-to-date test methods are used to assess their safety.

⁽¹⁾ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

- (24) The Commission and the Authority should be subject to deadlines to guarantee a smooth processing of applications. However, in certain cases, the Commission and the Authority should have the right to extend those deadlines.
- (25) The applicant may be requested by the Authority or by the Commission to provide additional information for the purposes of risk assessment or risk management respectively. In case the applicant fails to provide the additional information, as required, within the period set by the Authority or by the Commission after consulting the applicant, lack of such information may have consequences for the opinion of the Authority or for a possible authorisation and update of the Union list.
- (26) As regards the possible use of nanomaterials for food use, the Authority considered in its opinion of 6 April 2011 on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain that limited information is available in relation to aspects of nanotoxicokinetics and toxicology of engineered nanomaterials and that existing toxicity testing methods may need methodological modifications. The Organisation for Economic Cooperation and Development Council Recommendation of 19 September 2013 on the Safety Testing and Assessment of Manufactured Nanomaterials concluded that the approaches for the testing and assessment of traditional chemicals are, in general, appropriate for assessing the safety of nanomaterials, but may have to be adapted to the specificities of nanomaterials. In order to better assess the safety of nanomaterials for food use and in order to address the current gaps in toxicological knowledge and measurement methodologies, test methods, including non-animal tests, which take into account specific characteristics of engineered nanomaterials may be needed.
- (27) When test methods are applied to nanomaterials, an explanation should be provided by the applicant of their scientific appropriateness for nanomaterials and, where applicable, of the technical adaptations and adjustments that have been made in order to respond to the specific characteristics of those materials.
- (28) When a novel food is authorised and included in the Union list, the Commission should have the power to introduce post-market monitoring requirements to monitor the use of the authorised novel food to ensure that the use is within safe limits as established in the risk assessment by the Authority. Post-market monitoring requirements may therefore be justified by the necessity to gather information on the actual marketing of the food. In any event, food business operators should inform the Commission of any new relevant information regarding the safety of the food they have placed on the market.
- (29) New technologies and innovations in food production should be encouraged as they could reduce the environmental impact of food production, enhance food security and bring benefits to consumers as long as the high level of consumer protection is ensured.
- (30) Under specific circumstances, in order to stimulate research and development within the agri-food industry, and thus innovation, it is appropriate to protect the investment made by the applicants in gathering the information and data provided in support of an application for a novel food made in accordance with this Regulation. The newly developed scientific evidence and proprietary data provided in support of an application for inclusion of a novel food in the Union list should be protected. Those data and information should, for a limited period of time, not be used to the benefit of a subsequent applicant, without the agreement of the initial applicant. The protection of scientific data provided by an applicant should not prevent other applicants from seeking the inclusion of a novel food in the Union list on the basis of their own scientific data or by referring to the protected data with the agreement of the initial applicant. However, the overall five-year period of data protection which has been granted to the initial applicant should not be extended due to the granting of data protection to subsequent applicants.
- (31) In cases where an applicant requests the protection of scientific data relating to the same food in accordance with this Regulation and with Regulation (EC) No 1924/2006 of the European Parliament and of the Council⁽¹⁾, it should be possible for the respective data protection periods to run concurrently. Therefore, provision should be made for staying, on request by the applicant, the authorisation procedure for a novel food.

⁽¹⁾ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9).

- (32) In accordance with Directive 2010/63/EU of the European Parliament and of the Council ⁽¹⁾, tests on animals should be replaced, reduced or refined. Therefore, within the scope of this Regulation, duplication of animal testing should be avoided, where possible. Pursuing this goal could reduce possible animal welfare and ethical concerns with regard to novel food applications.
- (33) Novel foods are subject to the general labelling requirements laid down in Regulation (EU) No 1169/2011 and other relevant labelling requirements in Union food law. In certain cases it may be necessary to provide for additional labelling information, in particular regarding the description of the food, its source, its composition or its conditions of intended use to ensure that consumers are sufficiently informed of the nature and safety of the novel food, particularly with regard to vulnerable groups of the population.
- (34) Materials and articles intended to come into contact with novel foods are subject to Regulation (EC) No 1935/2004 of the European Parliament and of the Council ⁽²⁾ and the specific measures adopted thereunder.
- (35) In line with the Commission's better regulation policy, the Commission should carry out an *ex-post* evaluation of the implementation of this Regulation, addressing in particular the new procedures on traditional foods from third countries.
- (36) For those applications which have been submitted under Regulation (EC) No 258/97 and for which a final decision has not been taken before the date of application of this Regulation risk assessment and authorisation procedures should be concluded in accordance with this Regulation. Furthermore, a food not falling within the scope of Regulation (EC) No 258/97, which was lawfully placed on the market before the date of application of this Regulation and which falls under the scope of this Regulation, should in principle be allowed to continue to be placed on the market until the risk assessment and authorisation procedures under this Regulation have been concluded. Therefore, transitional provisions should be laid down to ensure a smooth transition to the rules of this Regulation.
- (37) This Regulation respects the fundamental rights and observes the principles recognised, in particular, by the Charter of Fundamental Rights of the European Union.
- (38) The Member States should lay down rules on penalties applicable to infringements of this Regulation and should take all measures necessary to ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.
- (39) In order to achieve the objectives of this Regulation, the power to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the adjustment and adaptation of the definition of engineered nanomaterial to technical and scientific progress or to definitions agreed at international level. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (40) In order to ensure uniform conditions for the implementation of this Regulation with regard to updating the Union list concerning the adding of a traditional food from a third country where no reasoned safety objections have been expressed, implementing powers should be conferred on the Commission.
- (41) The advisory procedure should be used for the adoption of the implementing act establishing the initial Union list given that it will concern only novel foods that have already been assessed for their safety, have been legally produced and marketed in the Union and have not given rise to health concerns in the past. The examination procedure should be used for the adoption of implementing acts in all other cases.

⁽¹⁾ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

⁽²⁾ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

- (42) Since the objectives of this Regulation, in particular the laying down of rules for the placing of novel foods on the market within the Union, cannot be sufficiently achieved by the Member States but can rather be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and purpose

1. This Regulation lays down rules for the placing of novel foods on the market within the Union.
2. The purpose of this Regulation is to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumers' interests.

Article 2

Scope

1. This Regulation applies to the placing of novel foods on the market within the Union.
2. This Regulation does not apply to:
 - (a) genetically modified foods falling within the scope of Regulation (EC) No 1829/2003;
 - (b) foods when and in so far as they are used as:
 - (i) food enzymes falling within the scope of Regulation (EC) No 1332/2008;
 - (ii) food additives falling within the scope of Regulation (EC) No 1333/2008;
 - (iii) food flavourings falling within the scope of Regulation (EC) No 1334/2008;
 - (iv) extraction solvents used or intended to be used in the production of foodstuffs or food ingredients and falling within the scope of Directive 2009/32/EC.

Article 3

Definitions

1. For the purposes of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 apply.
2. The following definitions also apply:
 - (a) 'novel food' means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of the following categories:
 - (i) food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997;
 - (ii) food consisting of, isolated from or produced from microorganisms, fungi or algae;

- (iii) food consisting of, isolated from or produced from material of mineral origin;
 - (iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:
 - traditional propagating practices which have been used for food production within the Union before 15 May 1997; or
 - non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;
 - (v) food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union;
 - (vi) food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;
 - (vii) food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances;
 - (viii) food consisting of engineered nanomaterials as defined in point (f) of this paragraph;
 - (ix) vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where:
 - a production process not used for food production within the Union before 15 May 1997 has been applied as referred to in point (a) (vii) of this paragraph; or
 - they contain or consist of engineered nanomaterials as defined in point (f) of this paragraph;
 - (x) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC;
- (b) 'history of safe food use in a third country' means that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one third country, prior to a notification referred to in Article 14;
- (c) 'traditional food from a third country' means novel food as defined in point (a) of this paragraph, other than novel food as referred to in points (a) (i), (iii), (vii), (viii), (ix) and (x) thereof which is derived from primary production as defined in point 17 of Article 3 of Regulation (EC) No 178/2002 with a history of safe food use in a third country;
- (d) 'the applicant' means the Member State, the third country or the interested party, which may represent several interested parties and has submitted to the Commission an application in accordance with Article 10 or 16 or a notification in accordance with Article 14;
- (e) 'valid' in respect to an application or a notification means an application or a notification which falls within the scope of this Regulation and contains the information required for risk assessment and authorisation procedure;

- (f) 'engineered nanomaterial' means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale.

Properties that are characteristic of the nanoscale include:

- (i) those related to the large specific surface area of the materials considered; and/or
- (ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material.

Article 4

Procedure for determination of novel food status

1. Food business operators shall verify whether or not the food which they intend to place on the market within the Union falls within the scope of this Regulation.
2. Where they are unsure whether or not a food which they intend to place on the market within the Union falls within the scope of this Regulation, food business operators shall consult the Member State where they first intend to place the novel food. Food business operators shall provide the necessary information to the Member State to enable it to determine whether or not a food falls within the scope of this Regulation.
3. In order to determine whether or not a food falls within the scope of this Regulation, Member States may consult the other Member States and the Commission.
4. The Commission shall, by means of implementing acts, specify the procedural steps of the consultation process provided for in paragraphs 2 and 3 of this Article, including deadlines and the means to make the status publicly available. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

Article 5

Implementing power concerning the definition of novel food

The Commission may decide, on its own initiative or upon a request by a Member State, by means of implementing acts, whether or not a particular food falls within the definition of novel food, as laid down in point (a) of Article 3(2). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

CHAPTER II

REQUIREMENTS FOR PLACING NOVEL FOODS ON THE MARKET WITHIN THE UNION

Article 6

Union list of authorised novel foods

1. The Commission shall establish and update a Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 7, 8 and 9 ('the Union list').
2. Only novel foods authorised and included in the Union list may be placed on the market within the Union as such, or used in or on foods, in accordance with the conditions of use and the labelling requirements specified therein.

*Article 7***General conditions for inclusion of novel foods in the Union list**

The Commission shall only authorise and include a novel food in the Union list if it complies with the following conditions:

- (a) the food does not, on the basis of the scientific evidence available, pose a safety risk to human health;
- (b) the food's intended use does not mislead the consumer, especially when the food is intended to replace another food and there is a significant change in the nutritional value;
- (c) where the food is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

*Article 8***Initial establishment of the Union list**

By 1 January 2018 the Commission shall, by means of an implementing act, establish the Union list by including in it the novel foods authorised or notified under Article 4, 5 or 7 of Regulation (EC) No 258/97, including any existing authorisation conditions.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 30(2).

*Article 9***Content and updating of the Union list**

1. The Commission shall authorise a novel food and update the Union list in accordance with the rules laid down in:
 - (a) Articles 10, 11 and 12 and, where applicable, Article 27; or
 - (b) Articles 14 to 19.
2. The authorisation of a novel food and updating of the Union list provided for in paragraph 1 shall consist of one of the following:
 - (a) adding a novel food to the Union list;
 - (b) removing a novel food from the Union list;
 - (c) adding, removing or changing the specifications, conditions of use, additional specific labelling requirements or post-market monitoring requirements associated with the inclusion of a novel food in the Union list.
3. The entry for a novel food in the Union list provided for in paragraph 2 shall include the specification of the novel food and, where appropriate:
 - (a) the conditions under which the novel food may be used, including in particular any requirements necessary to avoid possible adverse effects on particular groups of the population, the exceeding of maximum intake levels and risks in case of excessive consumption;
 - (b) additional specific labelling requirements to inform the final consumer of any specific characteristic or food property, such as the composition, nutritional value or nutritional effects and intended use of the food, which renders a novel food no longer equivalent to an existing food or of implications for the health of specific groups of the population;
 - (c) post-market monitoring requirements in accordance with Article 24.

CHAPTER III

AUTHORISATION PROCEDURES FOR A NOVEL FOOD

SECTION I

General rules

Article 10

Procedure for authorising the placing on the market within the Union of a novel food and updating the Union list

1. The procedure for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 9 shall start either on the Commission's initiative or following an application to the Commission by an applicant. The Commission shall make the application available to the Member States without delay. The Commission shall make the summary of the application, based on the information referred to in points (a), (b) and (e) of paragraph 2 of this Article, publicly available.

2. The application for an authorisation shall include:

- (a) the name and address of the applicant;
- (b) the name and description of the novel food;
- (c) the description of the production process(es);
- (d) the detailed composition of the novel food;
- (e) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;
- (f) where appropriate, the analysis method(s);
- (g) a proposal for the conditions of intended use and for specific labelling requirements which do not mislead the consumer or a verifiable justification why those elements are not necessary.

3. Upon request by the Commission, the European Food Safety Authority ('the Authority') shall give its opinion as to whether the update is liable to have an effect on human health.

4. When test methods are applied to engineered nanomaterials as referred to in points (a) (viii) and (ix) of Article 3(2), an explanation shall be provided by the applicants of their scientific appropriateness for nanomaterials and, where applicable, of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of those materials.

5. The procedure for authorising the placing on the market within the Union of a novel food and updating the Union list as provided for in Article 9 shall end with the adoption of an implementing act in accordance with Article 12.

6. By way of derogation from paragraph 5, the Commission may terminate the procedure at any stage, and decide not to proceed with an update, where it considers that such an update is not justified.

In such cases, where applicable, the Commission shall take account of the views of Member States, the Authority's opinion and any other legitimate factors relevant to the update under consideration.

The Commission shall inform the applicant and all Member States directly of the reasons for not considering the update to be justified. The Commission shall make the list of such applications publicly available.

7. The applicant may withdraw its application at any time, thereby terminating the procedure.

*Article 11***Opinion of the Authority**

1. Where the Commission requests an opinion from the Authority, it shall forward the valid application to the Authority without delay, and not later than one month after having verified its validity. The Authority shall adopt its opinion within nine months from the date of receipt of a valid application.
2. In assessing the safety of novel foods, the Authority shall, where appropriate, consider whether:
 - (a) the novel food concerned is as safe as food from a comparable food category already placed on the market within the Union;
 - (b) the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the Union;
 - (c) a novel food, which is intended to replace another food, does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.
3. The Authority shall forward its opinion to the Commission, to the Member States and, where applicable, to the applicant.
4. In duly justified cases, where the Authority requests additional information from the applicant, the nine-month period provided for in paragraph 1 may be extended.

After consulting the applicant, the Authority shall specify a period within which that additional information is to be provided and shall inform the Commission thereof.

Where the Commission does not object to the extension within eight working days of being informed by the Authority, the nine-month period provided for in paragraph 1 shall be automatically extended by that additional period. The Commission shall inform the Member States of that extension.

5. Where the additional information referred to in paragraph 4 is not provided to the Authority within the additional period referred to in that paragraph, the Authority shall draw up its opinion on the basis of the available information.
6. Where an applicant submits additional information on its own initiative, it shall send that information to the Authority.

In such cases, the Authority shall give its opinion within the nine-month period provided for in paragraph 1.

7. The Authority shall make the additional information provided in accordance with paragraphs 4 and 6 available to the Commission and to the Member States.

*Article 12***Authorisation of a novel food and updates of the Union list**

1. Within seven months from the date of publication of the Authority's opinion, the Commission shall submit to the committee referred to in Article 30(1) a draft implementing act authorising the placing on the market within the Union of a novel food and updating the Union list, taking into account the following:
 - (a) the conditions provided for in points (a) and (b) of Article 7 and, where applicable, in point (c) of that Article;
 - (b) any relevant provision of Union law, including the precautionary principle as referred to in Article 7 of Regulation (EC) No 178/2002;
 - (c) the Authority's opinion;
 - (d) any other legitimate factors relevant to the application under consideration.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 30(3).

2. Where the Commission has not requested an opinion from the Authority in accordance with Article 10(3), the seven-month period provided for in paragraph 1 of this Article shall start from the date on which a valid application is received by the Commission in accordance with Article 10(1).

Article 13

Implementing acts laying down administrative and scientific requirements for applications

By 1 January 2018, the Commission shall adopt implementing acts concerning:

- (a) the content, drafting and presentation of the application referred to in Article 10(1);
- (b) the arrangements for verifying the validity, without delay, of those applications;
- (c) the type of information to be included in the opinion of the Authority referred to in Article 11.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

SECTION II

Specific rules for traditional foods from third countries

Article 14

Notification of a traditional food from a third country

Instead of following the procedure referred to in Article 10, an applicant, who intends to place on the market within the Union a traditional food from a third country, may opt to submit a notification of that intention to the Commission.

The notification shall include the following information:

- (a) the name and address of the applicant;
- (b) the name and description of the traditional food;
- (c) the detailed composition of the traditional food;
- (d) the country or countries of origin of the traditional food;
- (e) documented data demonstrating the history of safe food use in a third country;
- (f) a proposal for the conditions of intended use and for specific labelling requirements, which do not mislead the consumer, or a verifiable justification why those elements are not necessary.

Article 15

Procedure for notifying the placing on the market within the Union of a traditional food from a third country

1. The Commission shall forward the valid notification provided for in Article 14 without delay, and not later than one month after having verified its validity, to the Member States and to the Authority.

2. Within four months from the date on which a valid notification is forwarded by the Commission in accordance with paragraph 1, a Member State or the Authority may submit to the Commission duly reasoned safety objections to the placing on the market within the Union of the traditional food concerned.

3. The Commission shall inform the applicant of any duly reasoned safety objection as soon as it is submitted. The Member States, the Authority and the applicant shall be informed of the outcome of the procedure referred to in paragraph 2.

4. Where no duly reasoned safety objections have been submitted in accordance with paragraph 2 within the time-limit laid down in that paragraph, the Commission shall authorise the placing on the market within the Union of the traditional food concerned and update the Union list without delay.

The entry in the Union list shall specify that it concerns a traditional food from a third country.

Where applicable, certain conditions for use, specific labelling requirements, or post-market monitoring requirements shall be specified.

5. Where duly reasoned safety objections have been submitted to the Commission in accordance with paragraph 2, the Commission shall not authorise the placing on the market within the Union of the traditional food concerned or update the Union list.

In that case, the applicant may submit an application to the Commission in accordance with Article 16.

Article 16

Application for the authorisation of a traditional food from a third country

Where the Commission, acting in accordance with Article 15(5), does not authorise the placing on the market within the Union of a traditional food from a third country or update the Union list, the applicant may submit an application including, in addition to the information already provided in accordance with Article 14, documented data relating to the duly reasoned safety objections submitted in accordance with Article 15(2).

The Commission shall, without delay, forward the valid application to the Authority and make it available to Member States.

Article 17

Opinion of the Authority on a traditional food from a third country

1. The Authority shall adopt its opinion within six months from the date of receipt of a valid application.
2. In assessing the safety of a traditional food from a third country, the Authority shall consider the following matters:
 - (a) whether the history of safe food use in a third country is substantiated by reliable data submitted by the applicant in accordance with Articles 14 and 16;
 - (b) whether the composition of the food and the conditions of its use do not pose a safety risk to human health in the Union;
 - (c) where the traditional food from the third country is intended to replace another food, whether it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.
3. The Authority shall forward its opinion to the Commission, the Member States and the applicant.
4. In duly justified cases, where the Authority requests additional information from the applicant, the six-month period provided for in paragraph 1 may be extended.

After consulting the applicant, the Authority shall specify a period within which that additional information is to be provided and shall inform the Commission thereof.

Where the Commission does not object to the extension within eight working days of being informed by the Authority, the six-month period provided for in paragraph 1 shall be automatically extended by that additional period. The Commission shall inform the Member States of that extension.

5. Where the additional information referred to in paragraph 4 is not provided to the Authority within the additional period referred to in that paragraph, the Authority shall draw up its opinion on the basis of the available information.

6. Where an applicant submits additional information on its own initiative, it shall send that information to the Authority.

In such cases, the Authority shall give its opinion within the six-month period provided for in paragraph 1.

7. The Authority shall make the additional information provided in accordance with paragraphs 4 and 6 available to the Commission and to Member States.

Article 18

Authorisation of a traditional food from a third country and updates of the Union list

1. Within three months of the date of publication of the Authority's opinion, the Commission shall submit to the committee referred to in Article 30(1) a draft implementing act authorising the placing on the market within the Union of the traditional food from a third country and updating the Union list, taking into account the following:

- (a) the conditions provided for in points (a) and (b) of Article 7 and, where applicable, point (c) of that Article;
- (b) any relevant provision of Union law, including the precautionary principle as referred to in Article 7 of Regulation (EC) No 178/2002;
- (c) the Authority's opinion;
- (d) any other legitimate factors relevant to the application under consideration.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 30(3).

2. By way of derogation from paragraph 1, the Commission may terminate the procedure at any stage and decide not to proceed with an update where it considers that such an update is not justified.

In such case, where applicable, the Commission shall take account of the views of Member States, the Authority's opinion and any other legitimate factors relevant to the update under consideration.

The Commission shall inform the applicant and all Member States directly of the reasons for not considering the update to be justified.

3. The applicant may withdraw its application referred to in Article 16 at any time, thereby terminating the procedure.

Article 19

Updates to the Union list as regards authorised traditional foods from third countries

Articles 10 to 13 apply to removing a traditional food from a third country from the Union list or to adding, removing or changing specifications, conditions of use, additional specific labelling requirements or post-market monitoring requirements associated with the inclusion of a traditional food from a third country on the Union list.

*Article 20***Implementing acts laying down administrative and scientific requirements concerning traditional foods from third countries**

By 1 January 2018 the Commission shall adopt implementing acts concerning:

- (a) the content, drafting and presentation of the notifications referred to in Article 14 and of applications referred to in Article 16;
- (b) the arrangements for verifying the validity, without delay, of those notifications and applications;
- (c) the arrangements for the exchange of information with the Member States and with the Authority for submitting duly reasoned safety objections as referred to in Article 15(2);
- (d) the type of information to be included in the opinion of the Authority referred to in Article 17.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

CHAPTER IV

ADDITIONAL PROCEDURAL RULES AND OTHER REQUIREMENTS*Article 21***Additional information concerning risk management**

1. Where the Commission requests from an applicant additional information on matters concerning risk management, it shall determine, together with the applicant, the period within which that information is to be provided.

In such cases, the period provided for in Article 12(1) or (2) or in Article 18(1) may be extended accordingly. The Commission shall inform the Member States of that extension and shall make the additional information available to Member States once it has been received.

2. Where the additional information referred to in paragraph 1 is not received within the additional period referred to in that paragraph, the Commission shall act on the basis of the available information.

*Article 22***Ad hoc extension of time periods**

In exceptional circumstances, the Commission may extend the time periods provided for in Articles 11(1), 12(1) or (2), 17(1) and 18(1) on its own initiative or, where applicable, at the Authority's request, where the nature of the matter in question justifies an appropriate extension.

The Commission shall inform the applicant and the Member States of the extension and the reasons therefor.

*Article 23***Confidentiality of applications for updates of the Union list**

1. Applicants may request confidential treatment of certain information submitted under this Regulation where disclosure of such information may harm their competitive position.

2. For the purposes of paragraph 1, applicants shall indicate which parts of the information provided they wish to be treated as confidential and provide all the necessary details to substantiate their request for confidentiality. Verifiable justification shall be given in such cases.

3. After being informed of the Commission's position on the request, applicants may withdraw their application within three weeks, during which the confidentiality of the information provided shall be observed.

4. After expiry of the period referred to in paragraph 3, if an applicant has not withdrawn the application and in case of disagreement the Commission shall decide which parts of the information are to remain confidential and, in case a decision has been taken, notify the Member States and the applicant accordingly.

However, confidentiality shall not apply to the following information:

- (a) the name and address of the applicant;
- (b) the name and description of the novel food;
- (c) the proposed conditions of use of the novel food;
- (d) a summary of the studies submitted by the applicant;
- (e) the results of the studies carried out to demonstrate the safety of the food;
- (f) where appropriate, the analysis method(s);
- (g) any prohibition or restriction imposed in respect of the food by a third country.

5. The Commission, the Member States and the Authority shall take necessary measures to ensure appropriate confidentiality of the information as referred to in paragraph 4 and received by them under this Regulation, except for information which is required to be made public in order to protect human health.

6. Where an applicant withdraws, or has withdrawn, its application, the Commission, the Member States and the Authority shall not disclose confidential information, including the information whose confidentiality is the subject of disagreement between the Commission and the applicant.

7. The application of paragraphs 1 to 6 shall not affect the exchange of information concerning the application between the Commission, the Member States and the Authority.

8. The Commission may, by means of implementing acts, adopt detailed rules on the implementation of paragraphs 1 to 6.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

Article 24

Post-market monitoring requirements

The Commission may, for food safety reasons and taking into account the opinion of the Authority, impose post-market monitoring requirements. Such requirements may include, on a case-by-case basis, the identification of the relevant food business operators.

Article 25

Additional information requirements

Any food business operator which has placed a novel food on the market shall immediately inform the Commission of any information of which it has become aware concerning:

- (a) any new scientific or technical information which might influence the evaluation of the safety of use of the novel food;
- (b) any prohibition or restriction imposed by a third country in which the novel food is placed on the market.

The Commission shall make that information available to the Member States.

CHAPTER V

DATA PROTECTION*Article 26***Authorisation procedure in case of data protection**

1. On request by the applicant, and where supported by appropriate and verifiable information included in the application provided for in Article 10(1), newly developed scientific evidence or scientific data supporting the application shall not be used for the benefit of a subsequent application during a period of five years from the date of the authorisation of the novel food without the agreement of the initial applicant.
2. The data protection shall be granted by the Commission under Article 27(1) where the following conditions are met:
 - (a) the newly developed scientific evidence or scientific data was designated as proprietary by the initial applicant at the time the first application was made;
 - (b) the initial applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made; and
 - (c) the novel food could not have been assessed by the Authority and authorised without the submission of the proprietary scientific evidence or scientific data by the initial applicant.

However, the initial applicant may agree with a subsequent applicant that such scientific evidence and scientific data may be used.

3. Paragraphs 1 and 2 shall not apply to notifications and applications concerning the placing on the market within the Union of traditional foods from third countries.

*Article 27***Authorisation of a novel food and inclusion in the Union list based on protected proprietary scientific evidence or scientific data**

1. Where a novel food is authorised and included in the Union list pursuant to Articles 10 to 12 based on proprietary scientific evidence or scientific data that are granted data protection as provided for in Article 26(1), the entry of that novel food in the Union list shall indicate, in addition to the information referred to in Article 9(3):
 - (a) the date of inclusion of the novel food in the Union list;
 - (b) the fact that that inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26;
 - (c) the name and address of the applicant;
 - (d) the fact that during the period of data protection the novel food is authorised for placing on the market within the Union only by the applicant specified in point (c) of this paragraph, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 or with the agreement of the initial applicant;
 - (e) the end date of the data protection provided for in Article 26.
2. Scientific evidence or scientific data protected in accordance with Article 26 or for which the protection period under that Article has expired shall not be granted renewed protection.

*Article 28***Authorisation procedure in case of a parallel application for the authorisation of a health claim**

1. The Commission shall, on request by the applicant, stay an authorisation procedure for a novel food started following an application, where the applicant has submitted:

- (a) a request for data protection in accordance with Article 26; and
- (b) an application for the authorisation of a health claim on the same novel food in accordance with Article 15 or 18 of Regulation (EC) No 1924/2006, in conjunction with a request for data protection in accordance with Article 21 of that Regulation.

The stay of the authorisation procedure shall be without prejudice to the assessment of the food by the Authority in accordance with Article 11.

2. The Commission shall inform the applicant about the date of effect of the stay.

3. While the authorisation procedure is stayed, time shall cease to run for the purposes of the time-limit laid down in Article 12(1).

4. The authorisation procedure shall resume when the Commission has received the opinion of the Authority on the health claim pursuant to Regulation (EC) No 1924/2006.

The Commission shall inform the applicant about the date of resumption of the authorisation procedure. From the date of resumption, time shall begin to run afresh from the beginning for the purposes of the time-limit laid down in Article 12(1) of this Regulation.

5. In the cases referred to in paragraph 1 of this Article, where data protection has been granted in accordance with Article 21 of Regulation (EC) No 1924/2006, the period of data protection granted in accordance with Article 26 of this Regulation shall not exceed the period of data protection granted in accordance with Article 21 of Regulation (EC) No 1924/2006.

6. The applicant may withdraw at any time the request for staying the authorisation procedure submitted in accordance with paragraph 1. In that case, the authorisation procedure shall resume and paragraph 5 shall not apply.

CHAPTER VI

PENALTIES AND GENERAL PROVISIONS*Article 29***Penalties**

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 1 January 2018 and shall notify it without delay of any subsequent amendment affecting them.

*Article 30***Committee procedure**

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾.

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Article 31

Delegated acts

For the purposes of achieving the objectives of this Regulation, the Commission shall, by means of delegated acts adopted in accordance with Article 32, adjust and adapt the definition of engineered nanomaterials referred to in point (f) of Article 3(2) to technical and scientific progress or to definitions agreed at international level.

Article 32

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. It is of particular importance that the Commission follow its usual practice and carry out consultations with experts, including Member States' experts, before adopting those delegated acts.
3. The power to adopt delegated acts referred to in Article 31 shall be conferred on the Commission for a period of five years from 31 December 2015. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
4. The delegation of power referred to in Article 31 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or on a later date specified therein. It shall not affect the validity of any delegated acts already in force.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 31 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and to the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

CHAPTER VII

TRANSITIONAL MEASURES AND FINAL PROVISIONS*Article 33***Amendments to Regulation (EU) No 1169/2011**

Regulation (EU) No 1169/2011 is amended as follows:

(1) In Article 2(1) the following point is added:

‘(h) the definition of “engineered nanomaterials” as established by point (f) of Article 3(2) of Regulation (EU) 2015/2283 of the European Parliament and of the Council (*).

(*) Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).’.

(2) Point (t) of Article 2(2) is deleted.

References to the deleted point (t) of Article 2(2) of Regulation (EU) No 1169/2011 shall be construed as references to point (f) of Article 3(2) of this Regulation.

(3) In Article 18, paragraph 5 is deleted.

*Article 34***Repeal**

Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001 are hereby repealed from 1 January 2018. References to Regulation (EC) No 258/97 shall be construed as references to this Regulation.

*Article 35***Transitional measures**

1. Any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not been taken before 1 January 2018 shall be treated as an application under this Regulation.

The Commission shall not apply Article 11 of this Regulation, where a risk assessment has already been provided by a Member State on the basis of Regulation (EC) No 258/97 and no other Member State has raised any reasoned objection to that assessment.

2. Foods not falling within the scope of Regulation (EC) No 258/97, which are lawfully placed on the market by 1 January 2018 and which fall within the scope of this Regulation may continue to be placed on the market until a decision is taken in accordance with Articles 10 to 12 or Articles 14 to 19 of this Regulation following an application for authorisation of a novel food or a notification of a traditional food from a third country submitted by the date specified in the implementing rules adopted in accordance with Article 13 or 20 of this Regulation respectively, but no later than 2 January 2020.

3. The Commission may, by means of implementing acts, adopt measures concerning the requirements referred to in Articles 13 and 20 necessary for the application of paragraphs 1 and 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

*Article 36***Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2018, except for the following provisions:

- (a) Article 4(4), Articles 8, 13 and 20, Article 23(8), Article 30 and Article 35(3) shall apply from 31 December 2015;
- (b) Article 4(2) and (3) shall apply from the date of application of the implementing acts referred to in Article 4(4);
- (c) Article 5 shall apply from 31 December 2015. However, implementing acts adopted under Article 5 shall not apply before 1 January 2018;
- (d) Articles 31 and 32 shall apply from 31 December 2015. However, delegated acts adopted under those Articles shall not apply before 1 January 2018.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 25 November 2015.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
N. SCHMIT
