



BREXIT DEAL OR NO DEAL



B-DAY

MARCH 29, 2019

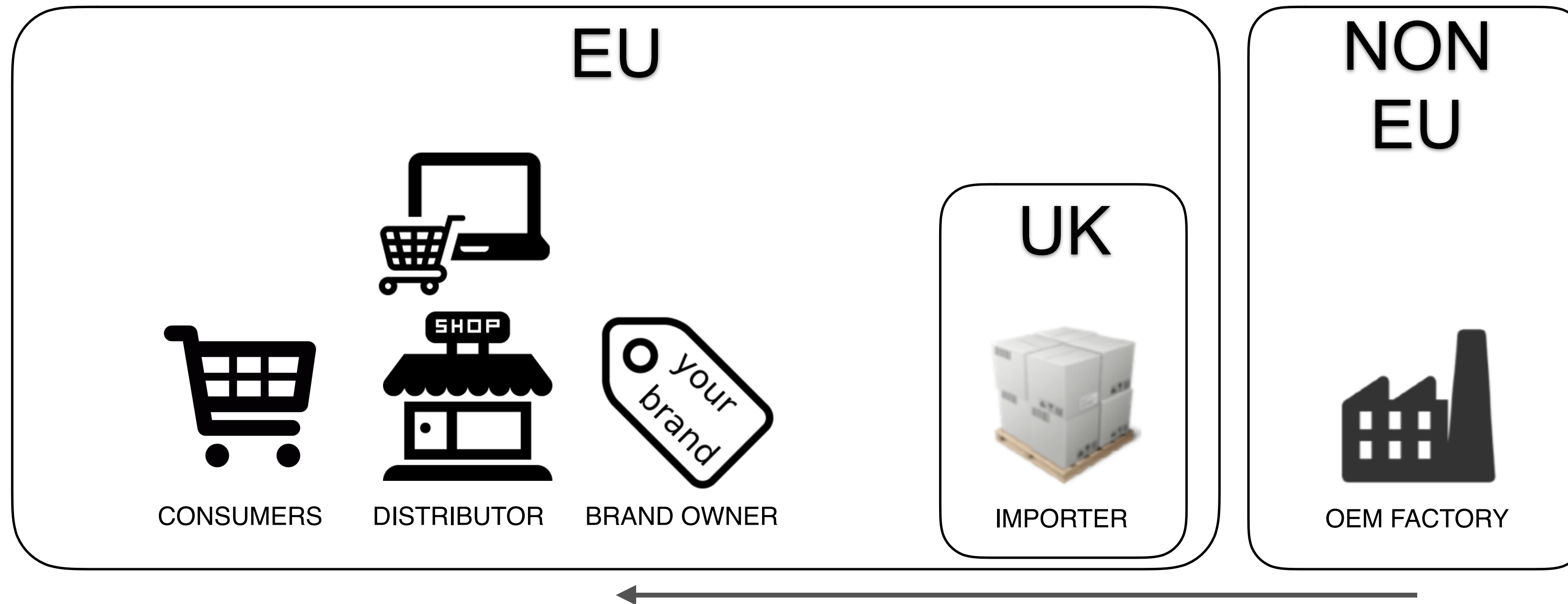


TWO SCENARIOS*

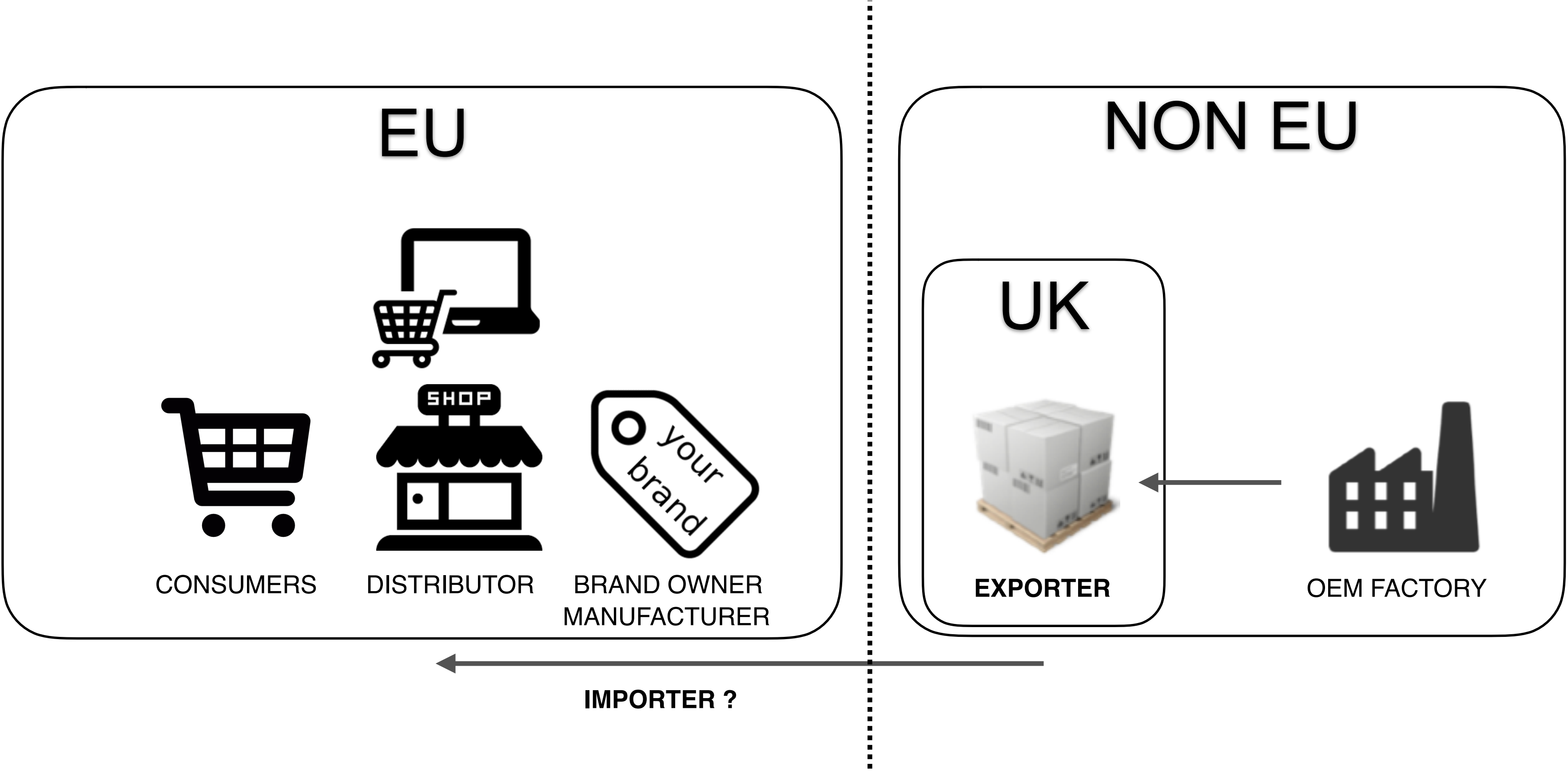
- NO DEAL (HARD) BREXIT
- DEAL BREXIT

DOES IT MAKE A DIFFERENCE?

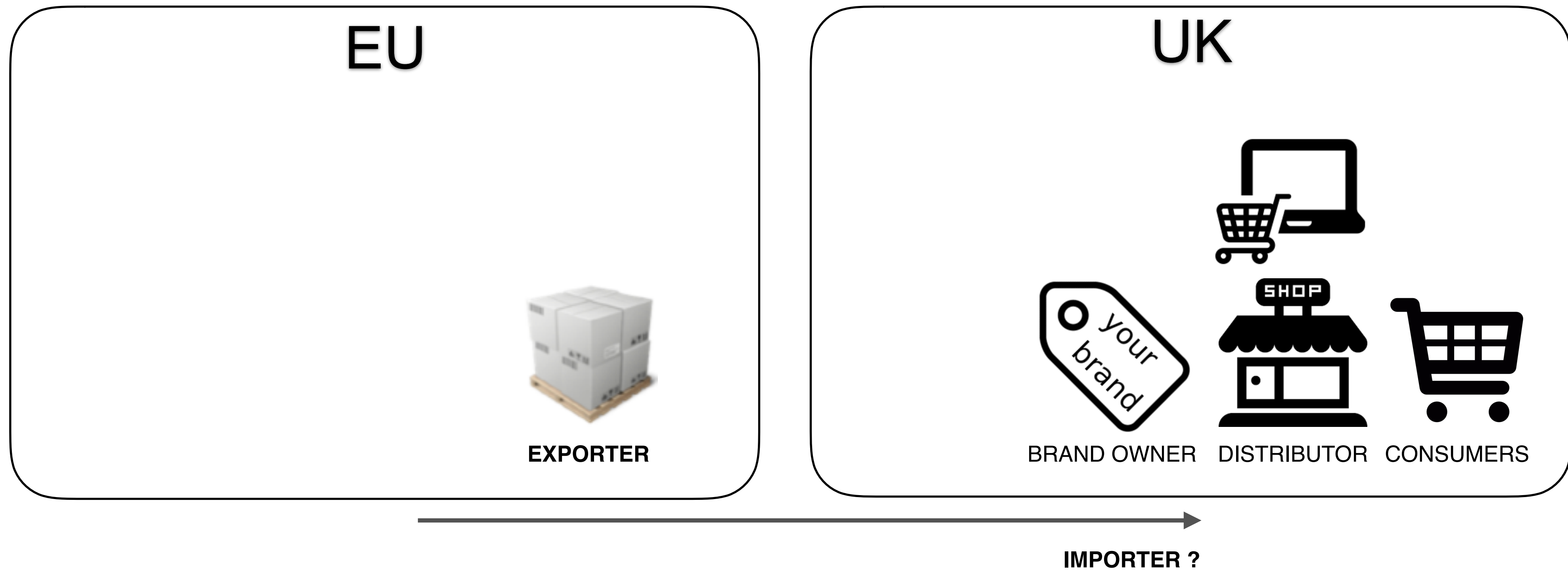
ROLES IN THE SUPPLY CHAIN



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ROLES IN THE SUPPLY CHAIN

- MATCH ROLE AND ADDRESS INFO
 - EU DoC (CE marking) (to EU)
 - UK DoC (UK marking) (to UK)
- but what about the requirements?

source: <https://www.gov.uk/government/publications/uk-governments-preparations-for-a-no-deal-scenario/uk-governments-preparations-for-a-no-deal-scenario>

THE NEW APPROACH RANGE

- Regulation for Accreditation and Market Surveillance – 765/2008
- Toy Safety - Directive 2009/48/EU
- Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU
- Pyrotechnic Articles - Directive 2013/29/EU
- Recreational craft and personal watercraft - Directive 2013/53/EU
- Civil Explosives - Directive 2014/28/EU
- Simple Pressure Vessels - Directive 2014/29/EU
- Electromagnetic Compatibility - Directive 2014/30/EU
- Non-automatic Weighing Instruments - Directive 2014/31/EU
- Measuring Instruments - Directive 2014/32/EU
- Lifts - Directive 2014/33/EU
- ATEX - Directive 2014/34/EU
- Radio equipment - Directive 2014/53/EU
- Low Voltage - Directive 2014/35/EU
- Pressure equipment - Directive 2014/68/EU
- Marine Equipment - Directive 2014/90/EU
- Personal protective equipment - Regulation (EU) 2016/425
- Gas appliances - Regulation (EU) 2016/426
- Machinery Directive – Directive 2006/42/EC
- Noise emission in the environment by equipment for use outdoors – Directive 2000/14/EC
- Ecodesign directive – (2009/125/EC)



THE NEW APPROACH RANGE

From EU to UK - products with self-certification based on EU harmonised standards

- 18 months transition period
- Products that meet EU requirements can continue to be placed on the UK market without any need for reassessment or re-marking
- Importers of products from the EU may put information identifying them on an accompanying document (rather than the product itself).

This transitional measure only applies to businesses who import products to the UK from the EU (including the EEA).

source: <https://www.gov.uk/government/publications/trading-goods-regulated-under-the-new-approach-if-theres-no-brex-it-deal>



THE NEW APPROACH RANGE

From EU to UK - products with self-certification based on EU harmonised standards

- After this transition period there will be a UK marking
- There will be a kind of a UK DoC
- UK won't have Harmonised Standards but Designated Standards

(UK will continue to participate in CEN, CENELEC and ETSI standardisation work)

THE NEW APPROACH RANGE

From EU to UK - products that require approval by a Notified Body

- Products that meet EU requirements and bear a CE marking can be placed on the market during this transition period.
- Products that meet UK requirements and bear a UK conformity marking can be placed on the UK market, as long as any third-party assessment required has been carried out by a UK-recognised conformity assessment body

THE NEW APPROACH RANGE

From UK to EU

- UK entities can still use CE marking based on self-declaration when exporting goods however the information on the packaging needs to match the roles in the supply chain. Their customer (you?) most likely previously acted as “distributor” and now as “importer”
- Products assessed by a UK Notified Body will need to be reassessed by an EU-notified body (see NANDO database) because there won't be any UK Notified Bodies after Brexit
- The CE marking will have to have the reference with 4 digits of the new NB

THE NON HARMONISED RANGE

From EU to UK - Within the EEA it is called "Mutual Recognition Regulation"

- such as pet animals, foodstuffs, furniture, fireworks, tobacco, vehicles, etc
- you need to follow the technical rules under UK law
- ensure import / brandname (manufacturer) address information is correct
- no transition !

source: <https://www.gov.uk/guidance/mutual-recognition-regulation-across-the-eea#technical-rules-for-specific-non-harmonised-products-in-the-uk>

THE NON HARMONISED RANGE

Some examples

- Pedal Bicycles
- Children Clothing
- Nightwear
- Medicines (Child Safety) Regulations
- Petroleum Spirit (Plastic Containers) Regulations
- Bunk Beds
- Cooking Utensils
- Furniture and Furnishings
- Oil heaters
- Pencils and Graphic Instruments
- Gas cooking appliances
- Heating appliances
- Plugs and Sockets

THE NON HARMONISED RANGE

From UK to EU - Within the EEA it is called "Mutual Recognition Regulation"

- such as pet animals, foodstuffs, furniture, fireworks, tobacco, vehicles, etc
- you need to follow the technical rules under EU law
- ensure that you meet the national requirements of the first country the products are going to be made available.
- ensure import / brandname (manufacturer) address information is correct

NOTIFIED BODIES

CURRENTLY 176 NOTIFIED BODIES IN THE UK. SOME OF THE MAIN CATEGORIES

- PERSONAL PROTECTIVE EQUIPMENT - 14
- TOYS - 9
- CONSTRUCTION PRODUCTS - 58 !!
- RADIO EQUIPMENT DIRECTIVE - 10
- PRESSURE EQUIPMENT - 28 !
- MEDICAL - 4
- GAS - 3

Nando website about Notified Bodies: <http://ec.europa.eu/growth/tools-databases/nando/>



NOTIFIED BODIES

- PERSONAL PROTECTIVE EQUIPMENT - 14

FOR PPE - ALL ISSUED CERTIFICATES ARE VALID FOR 5 YEARS*

* Note: 5 years after date of issue! Not 5 years after a March 29, 2019!

AUTOMOTIVE

- FOR AUTOMOTIVE (UK had been assigned #11)

THE e MARKING IS RESERVED FOR EEA MEMBER STATES

e11 ISSUED BY Vehicle Certification Agency (VCA) IS NO LONGER VALID

E11 MARKING (BASED UN-ECE REGULATION) STILL IS POSSIBLE.

- UK will continue to recognise UN-ECE approvals for systems and components. Expected transition period - 2 years - including provisional arrangements in case of a no-deal Brexit
- UK to EU > EU “may” accept previous VCA approvals. Advise: move to EU type approval authority
- EU to UK > need to request UK WVTA approval however expected to be administrative process only. Parts with EU type approvals expected to be accepted also after Brexit

source: <https://www.interregs.com/articles/spotlight/>

CONSTRUCTION PRODUCTS

From EU to UK

- All existing European harmonised standards will become UK 'designated standards'. This will mean that immediately following the UK's exit from the EU, the European harmonised standards and UK designated standards will be identical. The UK government will publish and maintain the list of UK designated standards. This will be a UK-wide approach with the standards applying at UK level.
- Goods legitimately affixed with CE marking already on the UK market before the UK leaves the EU on 29 March 2019 will be able to continue to circulate in the UK.
- Additionally, goods which are made and assessed against EU harmonised standards and legitimately carry the CE marking can continue to be placed on the UK market.
- It is intended that these arrangements will be for a time-limited period, but the draft legislation itself does not limit the duration of this provision.

source: <https://www.gov.uk/guidance/construction-products-regulation-if-there-is-no-brexit-deal>



REACH

From UK TO EU

- UK COMPANIES REGISTERED AT REACH NEED TO TRANSFER THEIR REGISTRATIONS TO AN EEA-BASED ORGANISATION

REACH

From EU to UK

- IT IS EXPECTED THAT THE UK WILL BUILD ITS OWN SYSTEM REPLACING ECHA
- RELEVANT FOR COMPANIES THAT BRING SUBSTANCES ON THE UK MARKET
- WILL FOLLOW THE SAME LOGIC INCLUDING REGISTRATION OF CHEMICALS
- INCLUDING DUTY TO REGISTER CHEMICALS FOR DOWNSTREAM USERS
- TRANSITION WINDOW
 - INITIAL REGISTRATION WITHIN 60 DAYS
 - NOTIFY BASIC DATA ON CHEMICALS WITHIN 180 DAYS
 - COMPLETE REGISTRATION WITHIN 2 YEARS

source: <http://www.hse.gov.uk/brexit/reach.htm>

REACH

UK

- IF YOU ARE A UK-BASED ONLY REPRESENTATIVE OF A NON-EU COMPANY YOU CAN NO LONGER ACT AS REPRESENTATIVE
- ONLY AN EU/EEA BASED COMPANY CAN REGISTER A SUBSTANCE. IT IS POSSIBLE TO APPOINT AN **OR** - AN **ONLY REPRESENTATIVE**

this is more than just a paper holding job !

<https://echa.europa.eu/only-representative-communication-supply-chain-who>

WHAT ABOUT EU-AR / UK-AR

EU AR = EU AUTHORISED REPRESENTATIVE

A SINGLE POINT OF CONTACT IN THE EU/EEA
FOR MARKET SURVEILLANCE AUTHORITIES

OBVIOUSLY A UK ENTITY CAN NO LONGER BE AN EU AR
BECAUSE THEY WON'T BE PART OF EU/EEA

WHY AN EU-AR?

THIS WAY YOU SEPARATE YOUR COMPLIANCE
COMMUNICATION FROM YOUR COMMERCIAL OPERATION

ONE SINGLE ADDRESS THAT DOES NOT NEED TO CHANGE
WHEN YOU WANT TO CHANGE YOUR COMMERCIAL
OPERATION

WHEN AN EU-AR?

- 2006/66/EC (battery)
- 2009/48/EC (toys)
- 2010/35/EU (pressure equipment)
- 2013/29/EU (pyrotechnics)
- 2013/53/EU (personal watercraft)
- 2014/28/EU (explosives)
- 2014/29/EU (simple pressure vessels)
- 2014/30/EU (EMC)
- 2014/31/EU (NAWI)
- 2014/32/EU (MID)
- 2014/33/EU (Lifts)
- 2014/34/EU (ATEX)
- 2014/35/EU (LVD)
- 2014/53/EU (RED)
- 2014/68/EU (PED)
- 2014/90/EU (Marine)
- (EU) 305/2011 (construction)
- (EU) 2016/424 (Cableway)
- (EU) 2016/425 (PPE)
- (EU) 2016/426 (Gas appliances)
- (EU) 2017/745 (Medical)
- (EU) 2017/746 (IVD)
- Noise
- Machinery
- Ecodesign
- Cosmetics

WHEN AN EU-AR?

NOTE.

MACHINE DIRECTIVE AND NOISE DIRECTIVE - THE CONTACT POINT IN THE EU FOR NON-EU MANUFACTURERS MUST BE MENTIONED ON THE EU DOC

MEDICAL DEVICES FOR NON-EU MANUFACTURERS. MUST DESIGNATE A SINGLE AUTHORISED REPRESENTATIVE.



ProductIP as EU AR

Exporters who sell to European markets choose ProductIP as their Authorised Representative because:

- They know that European importers prefer to work with suppliers who have a legal representation within Europe.
- They want to sell directly to European end consumers. In that case local representation is mandatory.
- They are tired of changing the labels and manuals for different importers/distributors.
- They do not want to share confidential product information with every distributor/importer/agent.
- They want to create, manage and share product technical files that are needed to prove compliance in the most efficient, proactive and transparent way possible.
- They take their role and responsibilities serious and want to show that to the European authorities.

contact us to learn more via info@productip.com



WHAT ABOUT EPR's

EXTENDED PRODUCER RESPONSIBILITIES (EPR)

WEEE
BATTERY DIRECTIVE
PACKAGING DIRECTIVE

THESE SCHEME'S OPERATE IN EACH OF THE MEMBER STATES.
THE EU/EEA ENTITY OWNING THE GOODS WHEN THEY ARE BEING IMPORTED
INTO ONE OF THE MEMBER STATES MUST TAKE CARE OF THIS.

WHAT ABOUT EPR's

THIS COULD REQUIRE NEW REGISTRATIONS ESPECIALLY FOR GERMANY

WEEE - STIFTUNGEAR
PACKAGING DIRECTIVE - VERPACKG

WHAT ABOUT PRODUCTIP?

UK NO LONGER PART OF EU/EEA

SEPARATE FILES TO BE MADE FOR UK

BASEFILES FUNCTIONALITY LIKE FOR ANY OTHER NON EU/EEA REGION

SEPARATE FILES, SEPARATE FAST/REVIEW/ORGANISE PROJECTS

WHAT ARE BASE FILES?

BASE FILES	EXTENDED FILES
Rest of world	European Economic Area
Generic product families	Specific product with detailed Q&A
Validity of documents only. Based on metadata	Daily check on relevancy of requirements as well as validity of documents based on metadata.
<p>Web-based supply chain collaboration. Verifeyer smart risk assessment forms. Document viewer with built-in redaction tool. Share information with customers, end-users, authorities. Supplier dashboard. Measure the performance of your suppliers and your team. And more, much more.</p>	

BASE FILES

Q1. Why is there no reference to product specific standards in Base files, like in Extended files for the EU?

A1. The basis of the legal framework for the EU is so that when you follow the correct procedures and use harmonised standards where available there is an assumption of compliance. Our advise for accessing those markets is to always cooperate with an independent 3rd party as it is their business to type test products against national requirements/standards. The base files help you to organise and review compliance evidence and make the collaboration with 3rd party service providers as well as suppliers, end users, customers and authorities efficient.

BASE FILES

Q2.Can I add product specific standards as placeholder in the base files?

A2. Yes you can select requirements from our database and add them manually to the file. If you have similar products you can use functions such as clone or copy/paste metadata to create files with the same requirement lists. Note that we currently do NOT monitor the status of manually added requirements. Not in base files, not in extended files

BASE FILES

Q3. Can I combine a file for EU/EEA with a base file?

A3. No you cannot. You can copy/paste documents using the clipboard functionality build in the platform.

BASE FILES

Q4. Are you offering services such as Connect, Review, Organise and FAST for Base Files?

A4. Yes we are.

CHECKLIST - BUYING FROM UK

- IS YOUR ROLE IMPORTER? - ADDRESS INFORMATION CORRECT?
- DO YOU HAVE ACCESS TO TECHNICAL FILE?

- ARE YOU ALSO BRAND-OWNER? - ADDRESS INFORMATION CORRECT?
- DO YOU HAVE ACCESS TO TECHNICAL FILE?
- CE ON THE PRODUCT. HAVE YOU SIGNED EU DoC?

- OR HAS YOUR UK SUPPLIER CREATED EU-AR?

- NOTIFIED BODY BASED COMPLIANCE. UK NB? CHANGE TO EU/EEA NB!

- REACH OBLIGATIONS? HAVE YOU REGISTERED?

- EPR OBLIGATIONS? HAVE YOU REGISTERED?

CHECKLIST - SELLING TO UK

- ❑ CE BASED COMPLIANCE - 18 MONTHS TIME
- ❑ YOUR UK CUSTOMER NEEDS TO INCLUDE THEIR ADDRESS INFORMATION
- ❑ NON CE BASE COMPLIANCE - ENSURE COMPLIANCE TO UK REGULATIONS

- ❑ CE MARKING > IN DUE TIME ADD UK MARKING
- ❑ EU DoC > IN DUE TIME GENERATE UK DoC EQUIVALENT

- ❑ ARE YOU BRAND-OWNER? - CONSIDER UK AR WHEN THIS BECOMES POSSIBLE

- ❑ NOTIFIED BODY BASED COMPLIANCE. EU/EEA NB? CHANGE TO UK EQUIVALANT!

- ❑ REACH OBLIGATIONS NOW? REGISTERED TO UK SYSTEM IN DUE TIME!

- ❑ EPR OBLIGATIONS? YOUR CUSTOMER HAS TO (CONTINUE) TO DEAL WITH THIS

ProductIP

Companies in retail and trade turn to ProductIP because it instantly creates an efficient workflow and ensures easy access to a comprehensive regulatory database.

#Brexit will change roles in the supply chain for retail and trade and as a result, other entities become responsible for demonstrating product compliance of non-food consumer goods.

Product compliance information has to be collected and shared efficiently between businesses.

Compliance evidence has to be reviewed. EU DoC's have to be drawn up and signed, distributed with the product or otherwise be made available.

Our label/packaging/manual check ensure that information is in line with EU and national regulations and the new supply chain roles.

Some opt for ProductIP as EU Authorised Representative now that they have to change address information anyway.





@ProductIP and @CasparTerHorst

www.productip.com

#ComplianceTuesday

#WeLoveProductCompliance

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