

WEBINAR

Botanical extracts in pet food formulations: *regulatory framework, benefits and trends*

19th May 2021, 11.30 am



Mattia Saporiti
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Violetta Insolita
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The webinar is divided in 3 talks

1. Complementary feed for pets: regulatory framework & formulation development

Mattia Saporiti, Head of Regulatory Affairs and Formulation Development



2. Immunity and inflammation: overview of dogs and cats applications

Maddalena De' Cillà, Head of Clinical Product Development



3. EPO's extracts: how to claim the high-quality ingredients

Violetta Insolia, Product and Marketing Specialist EPO Srl



Complementary feed for pets: regulatory framework & formulation development

Mattia Saporiti

Head of Regulatory Affairs and Formulation Development

SAPORITI CONSULTING Srl



REGULATORY FRAMEWORK



LEGAL BASES ON PRODUCTION, LABELLING, MARKETING OF FEEDINGSTUFFS:

REGULATION (EC) 767/2009 : placing on the market and use of feed

COMMISSION REGULATION (EU) 2017/2279 : amending Annexes II, IV, VI, VII and VIII to Regulation (EC) No 767/2009

REGULATION (EC) 1069/2009: animal by-products and derived products not intended for human consumption



QUALITY REQUIREMENTS:

REGULATION (EC) 178/2002 : general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

REGULATION (EC) 183/2005 : requirements for feed hygiene

DIRECTIVE 2002/32 : undesirable substances



INGREDIENTS:

COMMISSION REGULATION (EU) 2017/1017 : Catalogue of feed materials

REGULATION (EC) 1831/2003 : additives for use in animal nutrition (ANNEX I + ANNEX II)

FEED MATERIAL REGISTER www.feedmaterialsregister.eu (Art. 24.6 Reg. (EC) 767/2009)



SOME DEFINITIONS



FEED:

Any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for ORAL FEEDING to animals

(Reg. 178/2002 art. 3.4)



FEED MATERIALS:

Products of vegetable or animal origin, whose principal objective is to meet animals nutrition needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixtures

(Reg. 767/2009 art. 3.2 g)



FEED ADDITIVES:

Substances, micro-organisms or preparation, other than feed materials and premixtures, which are intentionally added to feed or water in order to perform one or more of the following function ([Reg. 1831/2003 art. 2 + art. 5](#))

-favourably affect characteristic of feed

-favourably affect the colors of ornamental birds and fish

-satisfy the nutritional needs of animals

-favourably affect the environmental consequences of animal production

-favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs

-have a coccidiostatic or histomonostatic effect




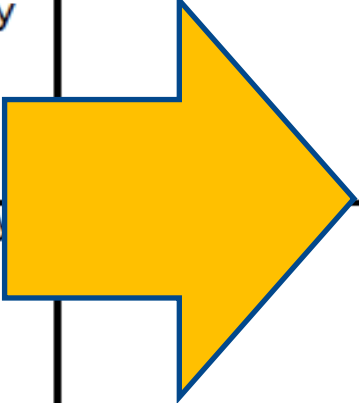



BOTANICAL EXTRACTS ARE FEED ADDITIVES:

REGULATION 1831/2003 Cat. 2b:

Flavouring compounds: substances the inclusion of which in feedingstuffs increases feed smell or palatability



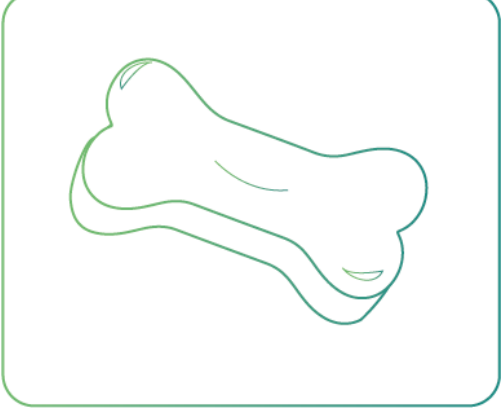
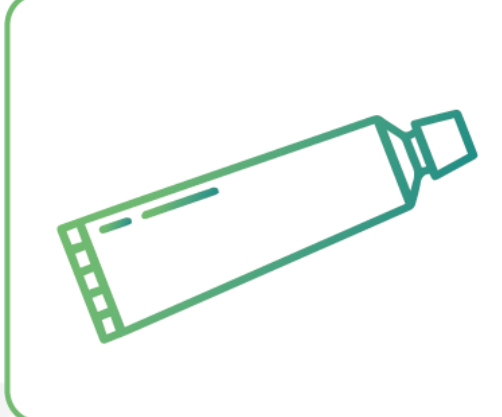
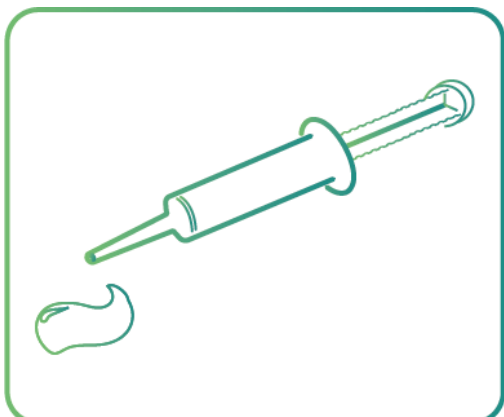
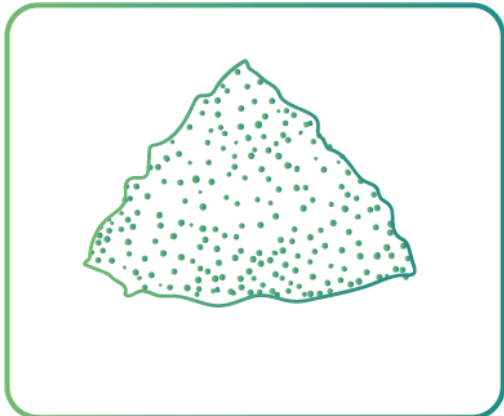
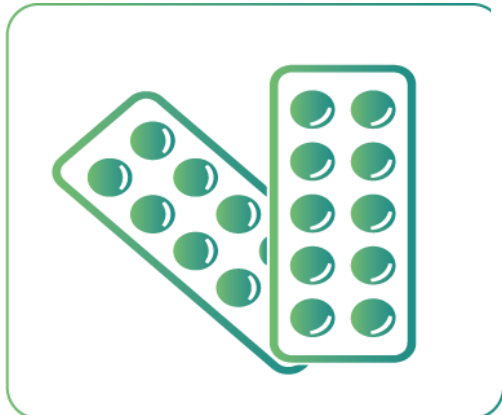
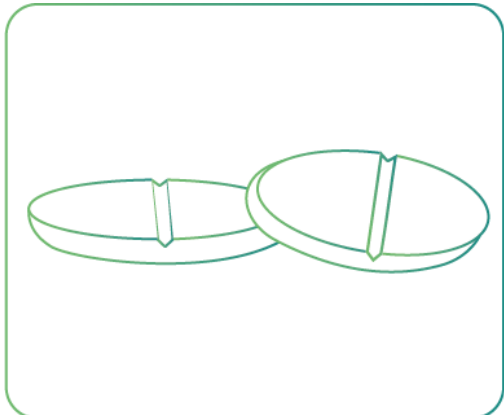
EXAMPLES OF BOTANICAL EXTRACTS AS ADDITIVES

Category	Functional Group	Subclassification	Code	Additive	Reference(s) of Community legal act	Reference in OJ	Date of authorisation	Expiry date of authorisation(s)	Date of first entry in the Register
(Annex I of Reg. 1831/03)									
2	b	Natural products – botanically defined		<i>Cynara scolymus</i> L.: Artichoke extract CoE 565 / Artichoke tincture CoE 565	Council Directive 70/524/EEC concerning additives in feedingstuffs – List of authorised additives in feedingstuffs (2004/C 50/01)	OJ C 50, 25.02.2004, p. 1	-	Following the provisions of Art. 10 § 2 of Reg. (EC) No 1831/2003, an application, in accordance with Article 7, has been submitted	07.11.05
2	b	Natural products – botanically defined		<i>Cytisus scoparius</i> (L.) Link: Common broom tincture CoE 170	Council Directive 70/524/EEC concerning additives in feedingstuffs – List of authorised additives in feedingstuffs (2004/C 50/01)	OJ C 50, 25.02.2004, p. 1	-	Following the provisions of Art. 10 § 2 of Reg. (EC) No 1831/2003, an application, in accordance with Article 7, has been submitted	07.11.05
2	b	Natural products – botanically defined		<i>Echinacea angustifolia</i> DC.: Blacksamson echinacea extract [Cats and dogs]	Council Directive 70/524/EEC concerning additives in feedingstuffs – List of authorised additives in feedingstuffs (2004/C 50/01)	OJ C 50, 25.02.2004, p. 1	-	Following the provisions of Art. 10 § 2 of Reg. (EC) No 1831/2003, an application, in accordance with Article 7, has been submitted	07.11.05
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2	b	Natural products – botanically defined		<i>Echinacea purpurea</i> (L.) Moench.: Echinacea absolute / Echinacea extract [Cats and dogs]	Council Directive 70/524/EEC concerning additives in feedingstuffs – List of authorised additives in feedingstuffs (2004/C 50/01)	OJ C 50, 25.02.2004, p. 1	-	Following the provisions of Art. 10 § 2 of Reg. (EC) No 1831/2003, an application, in accordance with Article 7, has been submitted	07.11.05
2	b	Natural products – botanically defined		<i>Harpagophytum procumbens</i> DC.: Devil's claw / grapple extract / Devil's claw / grapple tincture	Council Directive 70/524/EEC concerning additives in feedingstuffs – List of authorised additives in feedingstuffs (2004/C 50/01)	OJ C 50, 25.02.2004, p. 1	-	Following the provisions of Art. 10 § 2 of Reg. (EC) No 1831/2003, an application, in accordance with Article 7, has been submitted	07.11.05
2	b	Natural products – botanically defined		<i>Boswellia serrata</i> Roxb. ex Colebr.: Olibanum extract [All animal species]	Council Directive 70/524/EEC concerning additives in feedingstuffs – List of authorised additives in feedingstuffs (2004/C 50/01)	OJ C 50, 25.02.2004, p. 1	-	Following the provisions of Art. 10 § 2 of Reg. (EC) No 1831/2003, an application, in accordance with Article 7, has been submitted	07.11.05



OVERVIEW ON ADMINISTRATION FORMS (Dogs and cats)

COMPLETE FEED	SOLID FORM	DRY PET FOOD (KIBBLES)
	SEMI-SOLID FORM	WET PET FOOD (IN JELLY, IN GRAVY)
COMPLEMENTARY FEED	SOLID FORM	TABLETS
		CAPSULES
		SOFT-GEL
		POWDER IN MONO-DOSE SACHET
		POWDER IN JAR WITH MEASURING SPOON
		COOKIES
		SNACK&TREAT (DENTAL STICKS, BONES, ...)
	SEMI-SOLID FORM	PASTE IN MULTI-DOSE SYRINGE
		PASTE IN TUBE
		PASTE IN MONO-DOSE SACHET
		PASTE IN AIRLESS DISPENSER
		JELLY
	LIQUID FORM	LIQUID IN MONO-DOSE SACHET
		LIQUID IN BOTTLE WITH DROPPER
		LIQUID IN BOTTLE WITH MEASURING CUP



COMPLEMENTARY FEED DEVELOPMENT

COMPLEMENTARY FEED IS A COMPOUND FEED WHICH HAS A HIGH CONTENT OF CERTAIN SUBSTANCES BUT WHICH, BY REASON OF ITS COMPOSITION, IS SUFFICIENT FOR A DAILY RATION ONLY IF USED IN COMBINATION WITH OTHER FEED
(Reg. 767/2009 art. 3.2. j)

Analogy with **FOOD SUPPLEMENTS** in human sphere

COMPLEMENTARY FEED PRODUCT DEVELOPMENT REQUIRE A STRONG KNOWLEDGE OF :

- APPLICABLE REGULATION (additives values, allowed ingredients, ...)
- MANUFACTURING PROCESS
- TARGET SPECIES REQUIREMENTS (nutritional requirements)
- TARGET SPECIES REQUIREMENTS (behaviour)
- TARGET SPECIES REQUIREMENTS (palatability to achieve)
- SUPPLIERS OF ADDITIVES AND FEED MATERIALS (ingredients quality, ...)
- INGREDIENTS INTERACTION
- STABILITY OF THE FINAL PRODUCT (stability studies to guarantee the contents)

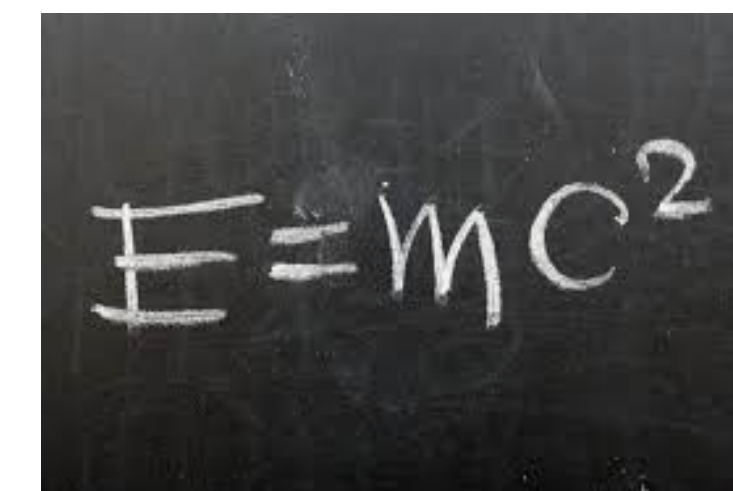


**FIND THE RIGHT
DOSAGE FORM**

**DEFINE THE RIGHT
FORMULA**



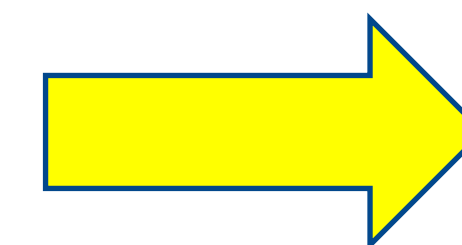
The «RIGHT FORMULA»



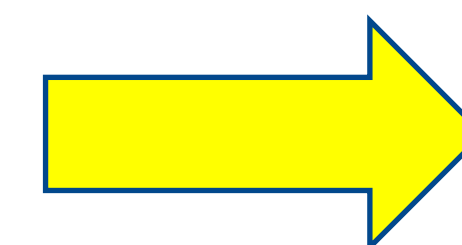
THE RIGHT FORMULA DOES NOT EXIST

THE RIGHT FORMULA IS A REFLECTION OF COMPANY VALUES ON:

- HISTORY OF THE BRAND
- INNOVATION STRATEGIES
- END PRODUCT DESIRED QUALITY & SAFETY
- END PRODUCT DESIRED EFFICACY
- END PRODUCT DESIRED PALATABILITY SCORE



**FIND THE RIGHT
DOSAGE FORM**



**DEFINE THE DESIRED
FORMULA**



HOW CAN I MAKE SURE THAT PETS WILL LIKE MY PRODUCTS?

This is a major question when creating a formula for pets

Making sure the pet will eat the product is at the heart of formula development in veterinary field



Palatability score is critical to the success of a product launch

ANIMAL SPECIFICITIES:

- Understanding the SENSORIAL, PHYSIOLOGICAL and BEHAVIOURAL specificities of cats and dogs is the key to design a veterinary product

PRODUCT FEATURES:

- **Palatant are your best friends** in veterinary pet formulation development
- Palatant are boosted by formula ingredients and by physical & chemical properties of the product and in some cases by the production process (heat treatments, moisture value, ...)
- Cover the bad taste of some functional ingredients is not easy: Palatability enhancements strategies must be applied



HOW CAN I MAKE SURE THAT PETS WILL LIKE MY PRODUCTS?

This is a major question when creating a formula for pets

PET OWNER EXPECTATION

- The rising pet parenting trend, requires market players to consider pet owner conception of pet food palatability performance
- Ease of use is part of the success of a new product
- To ensure product success, manufacturers must not only satisfy pet appetites, they also need this satisfaction to be shared and perceptible by the owner:

If the owners don't perceive that the animal loves the food, they will simply not repurchase it.

**POOR PALATABILITY AND POOR PRODUCT QUALITY
CAN RESULT IN BRAND DAMAGES AND LOSS OF CONSUMER TRUST**

(recalls, social-media post and negative feedback, ...)



DO I REALLY NEED TO WEAR A SEAT BELT ?

A discussion on Preservation and Quality of the products

The product's life can be seen as a journey by car, where the strategies to protect the product can be seen like a seat belt



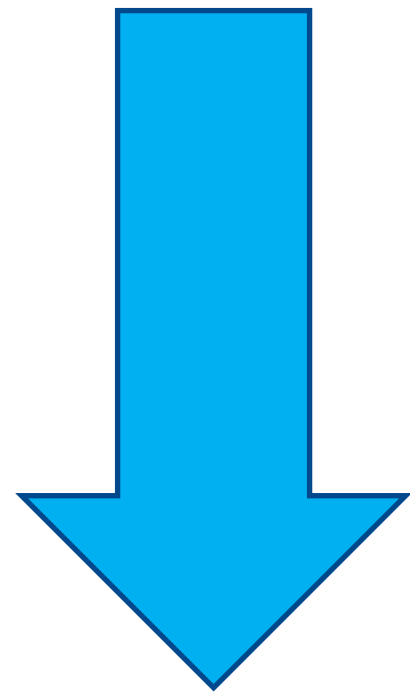
Like a seat belt **QUALITY STRATEGIES** are an essential tool to protect product quality during shelf-life.



DO I REALLY NEED TO WEAR A SEAT BELT ?

PREVENTION & PROTECTING STRATEGIES

- PREVENTION STRATEGIES:**
- Ingredients hygiene
 - Traceability of the ingredients
 - Unwanted substances
 - Bioburden of ingredients
 - Suppliers validation
 - Plant hygiene
 - Manufacturing process adequacy
 - Traceability of the process
 - Right choice of «active ingredients» and «excipients» (avoid incompatibility)
 - Right choice of packaging (avoid incompatibility and protect the product)



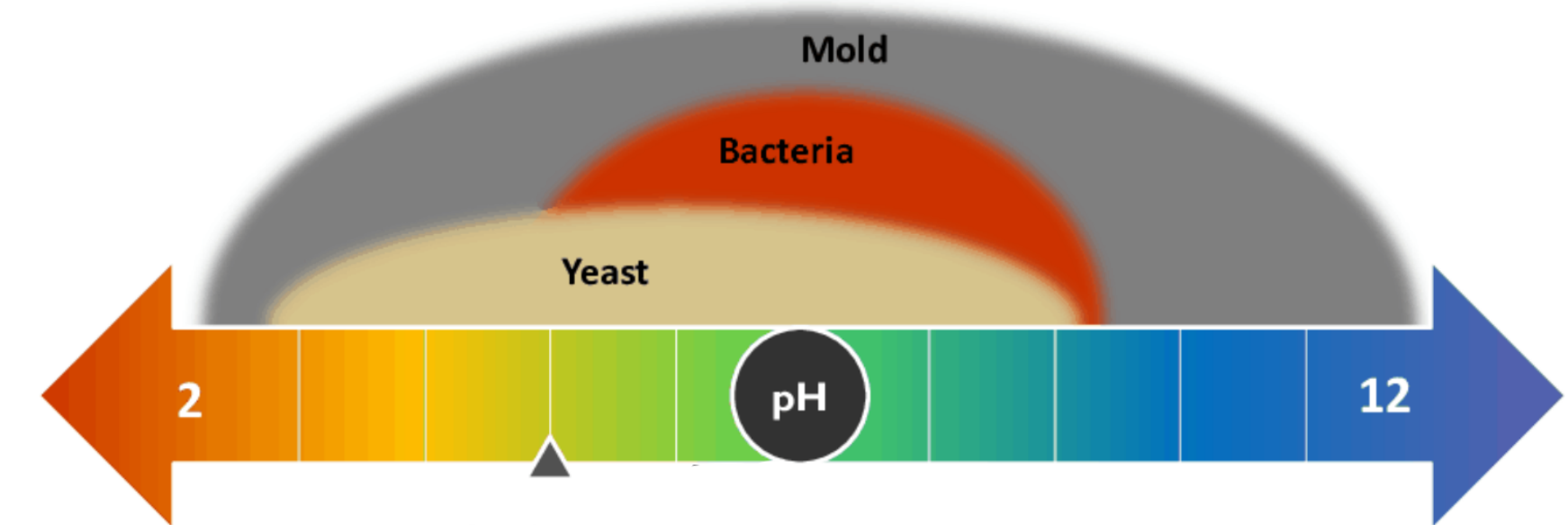
LOOK FOR INTERNATIONALLY RECOGNIZED STANDARD OF QUALITY FOR SUPPLIERS AND MANUFACTURERS



DO I REALLY NEED TO WEAR A SEAT BELT ?

- PROTECTING STRATEGIES:**
- use of preservatives
 - use of antioxidants
 - adequate pH values
 - adequate A_w values
 - right choice of packaging

Not all the authorized preservatives in human food supplements are authorized preservative additives in feedstuff regulation !



Product's pH and preservatives choice has impact on microbial activity and shelf-life stability of the final product.

POTASSIUM SORBATE: common preservative system in complementary feed formulation development, very effective on yeast and moulds with moderate activity on gram+ and gram– bacteria.

The efficacy depends on pH-value. The efficacy is increased by reducing the pH-Value. Only the free organic acids have biocidal activity (sorbic acid). The dissociated organic acid are completely ineffective. Potassium sorbate is used only to achieve faster incorporation in water based formula due to the better solubility in aqueous formulations. The subsequent pH adjustment with organic acids creates the effective undissociated sorbic acid.

Dosage of the preservatives:

- high levels than needed are not useful
- lower levels needed to be effective are the best choice



IS POSSIBLE DEVELOP A COMPLEMENTARY FEED WITHOUT PRESERVATIVES ?

- CONSIDERATION ABOUT:**
- Packaging choice (free head space, administration method, monodose, ...)
 - Ingredients stability
 - Ingredients suppliers (lowest bioburden, highest quality)
 - Final formula Water activity (A_w)
 - Final formula pH
 - Process hygiene and manufacturing process
 - Water based formula/ lipophilic formula /dry formula
 - Use of natural antioxidants (tocopherol rich extracts, ...)
 - ...

CASE by CASE EVALUATION



KNOWLEDGE MANAGEMENT

In feed development process



KNOWLEDGE MANAGEMENT is the process of capturing, distributing and effectively using **KNOWLEDGE**.

It has been a **key factor** in the successful development and manufacture of pharmaceutical products.

If applied to pet food and complementary feed development, it's possible to improve the product's performances in terms of quality, effectiveness, safety, regulatory compliance and shelf-life.

UNDERSTANDING THE CHEMICAL AND PHYSICAL PROCESSES UNDERLYING INTERACTIONS IN DOSAGE FORM FORMULATION, PRODUCTION PROCESS AND PRODUCT STORAGE THROUGHOUT THE SHELF-LIFE IS FUNDAMENTAL IN ASSURING

QUALITY – SAFETY - EFFICACY
OF A NEW PRODUCT.



TAKE-HOME MESSAGE



**FORMULATORS
OF
COMPLETE AND COMPLEMENTARY FEED
MUST CONSIDER
THE FULL FORMULA AND LIFESPAN
(from ingredients purchase to disposal)
TO PROVIDE A ROBUST SAFETY FRAMEWORK
AND
EXTEND PRODUCT QUALITY**



CONTACTS



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Immunity and inflammation: overview of dogs and cats applications

Maddalena De' Cillà DMV *Head of Clinical Product Development* SAPORITI CONSULTING Srl

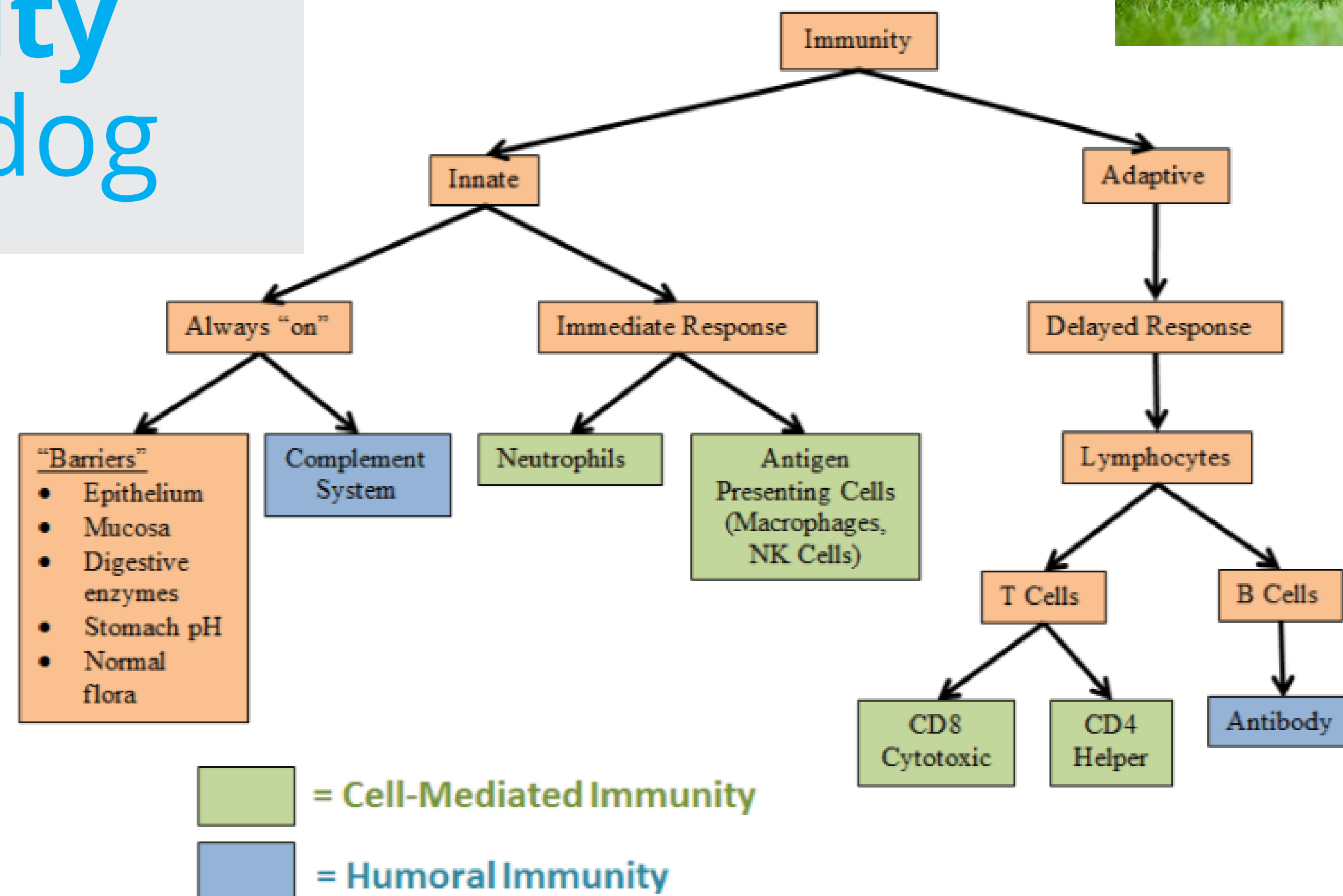
Immune system duty
is to spot intruders
and eliminate them!



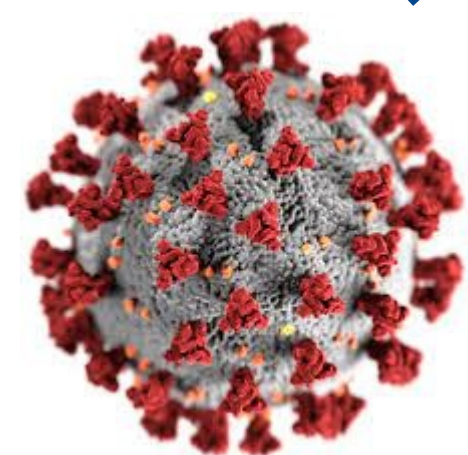
1. Immunity

Man and dog

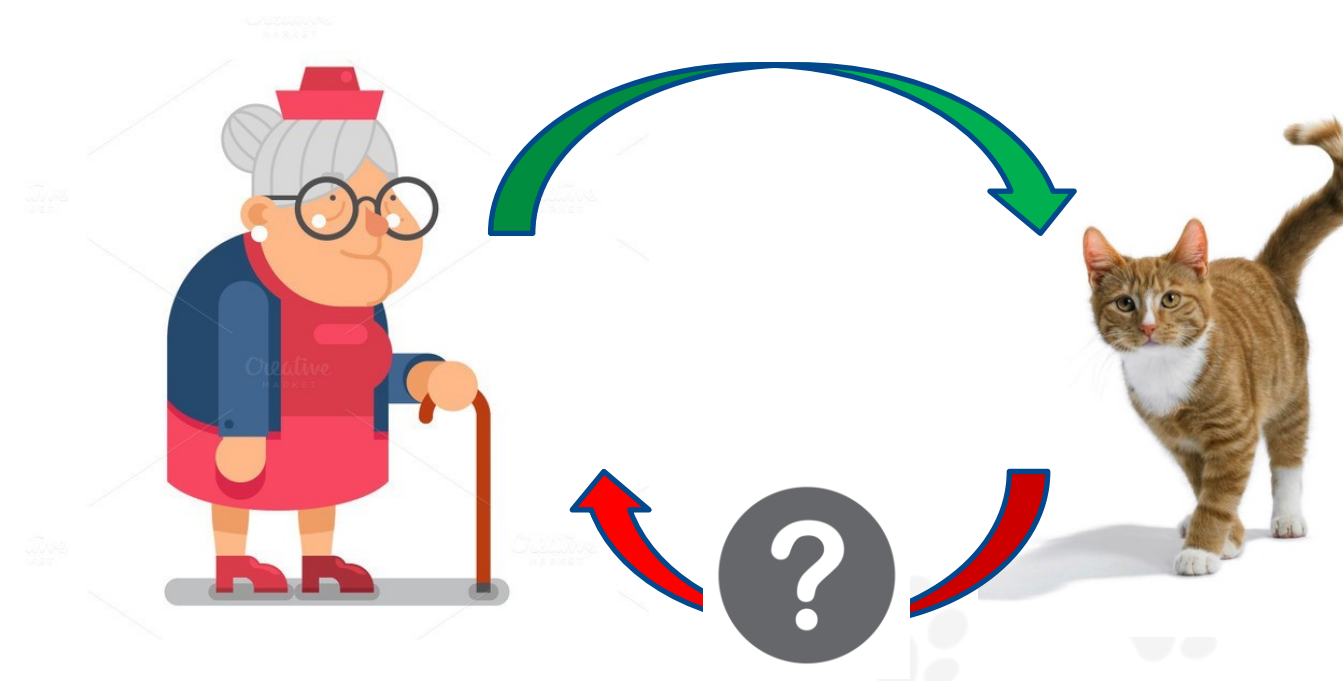
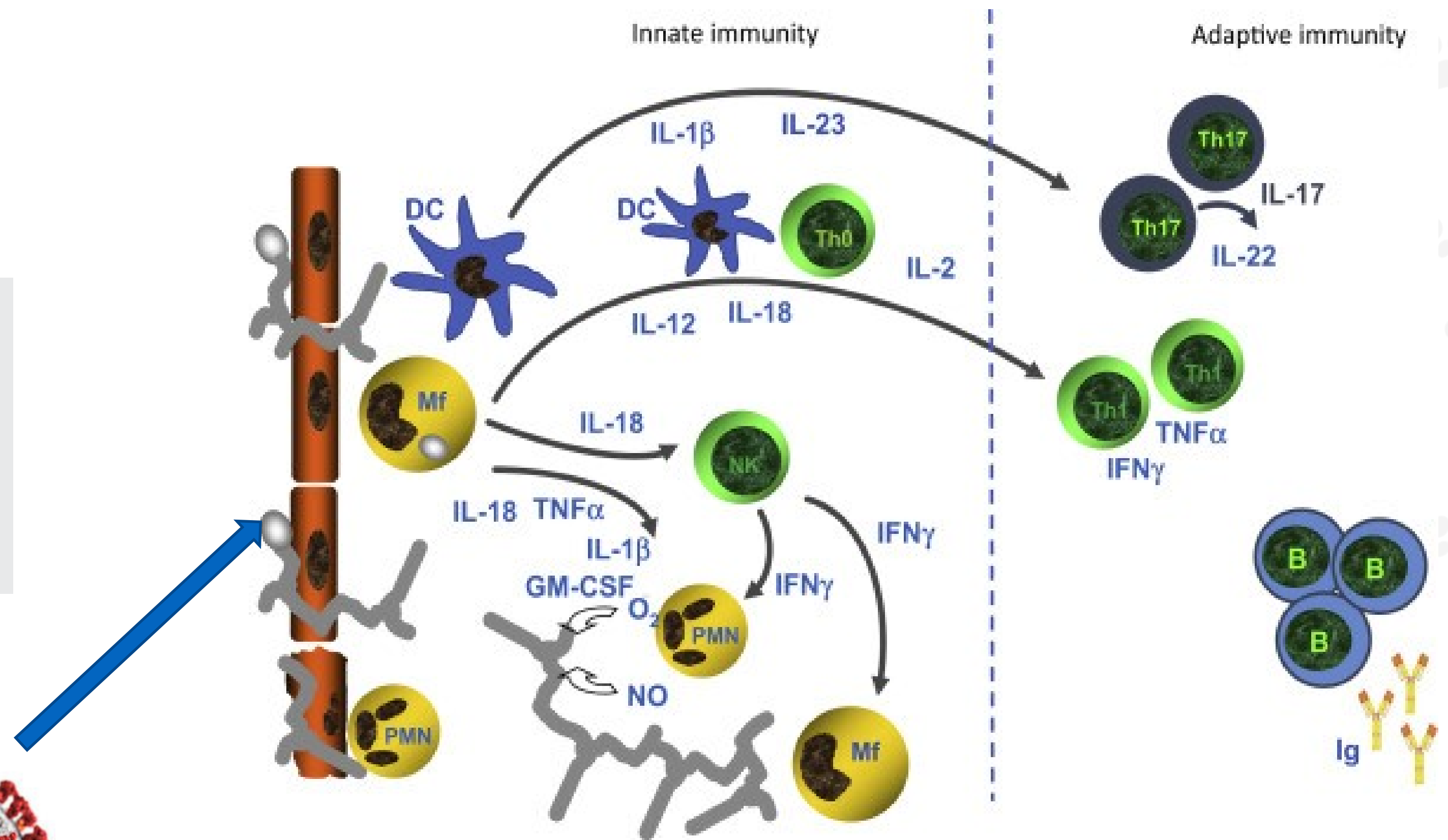
Dogs and human beings are fairly close
in terms of I.S. ontogenesis and function



1. Immunity: It's a crosstalk

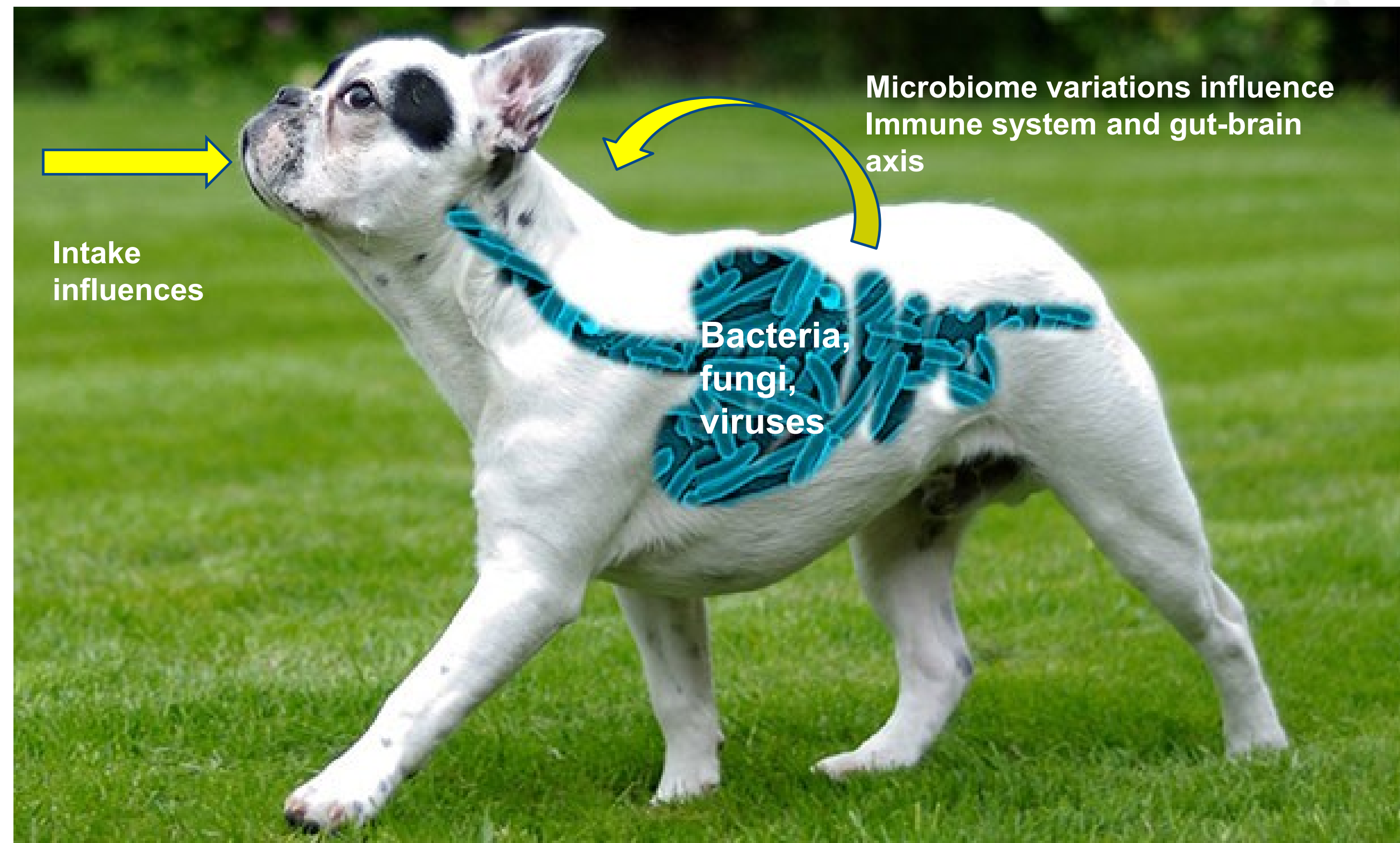


Sars CoV 19



3. Immunity

Gut microbiome



Any change in the G.M. composition that impacts its function it's called dysbiosis.

Alterations in bacteria derived metabolites , therefore, in microbiota function: due to micronutrients.

Body response to disease can be influenced by botanicals!

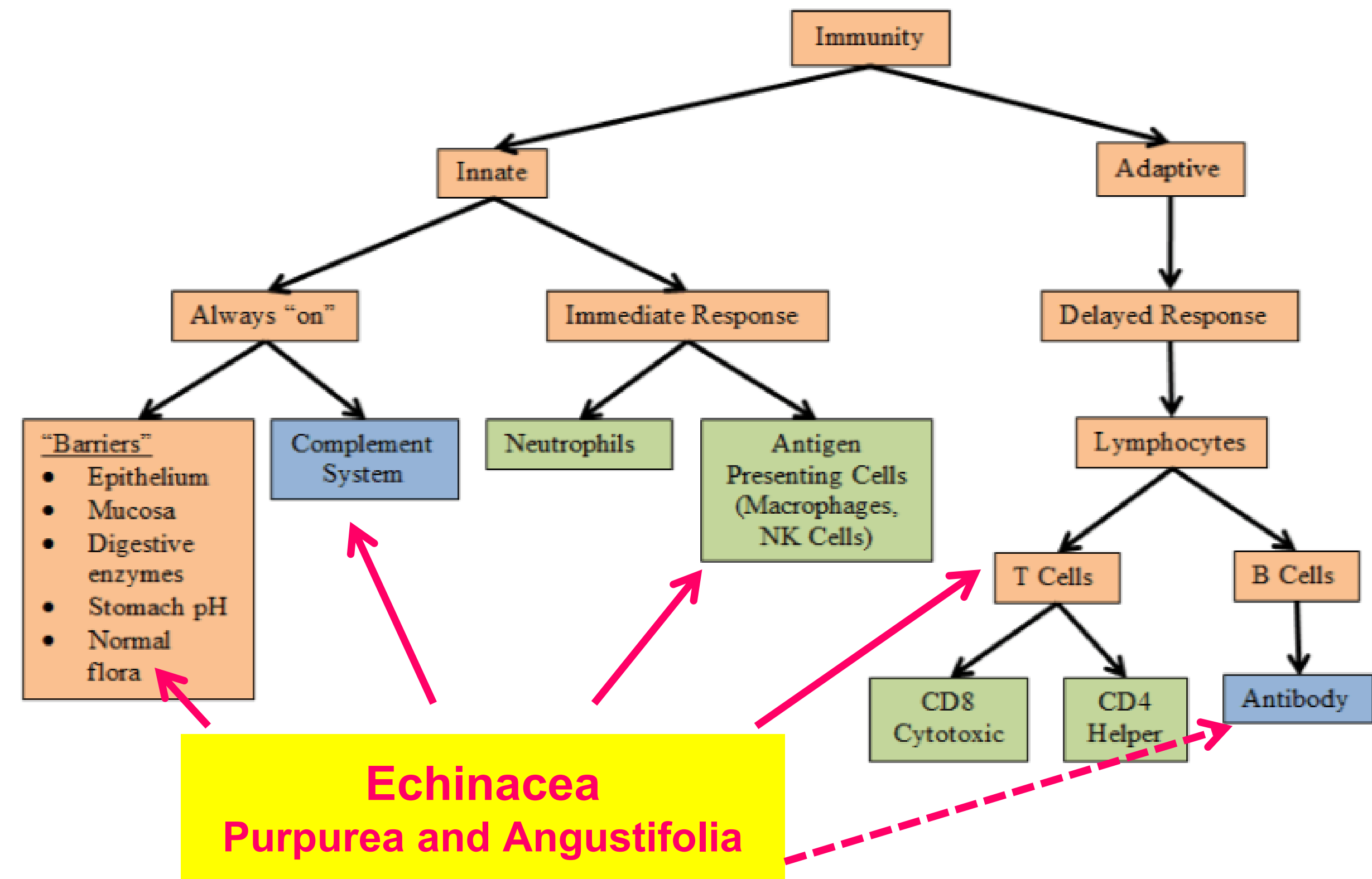


E.P. and E.A. Polyphenols, flavonoids and Pehnnolic acids:

Immunomodulatory activity in URTI treatment (2004: 400 pubs)

2. Herbal medicine

Echinacea Purpurea
Echinacea Angustifolia



3. Inflammation Osteoarthritis

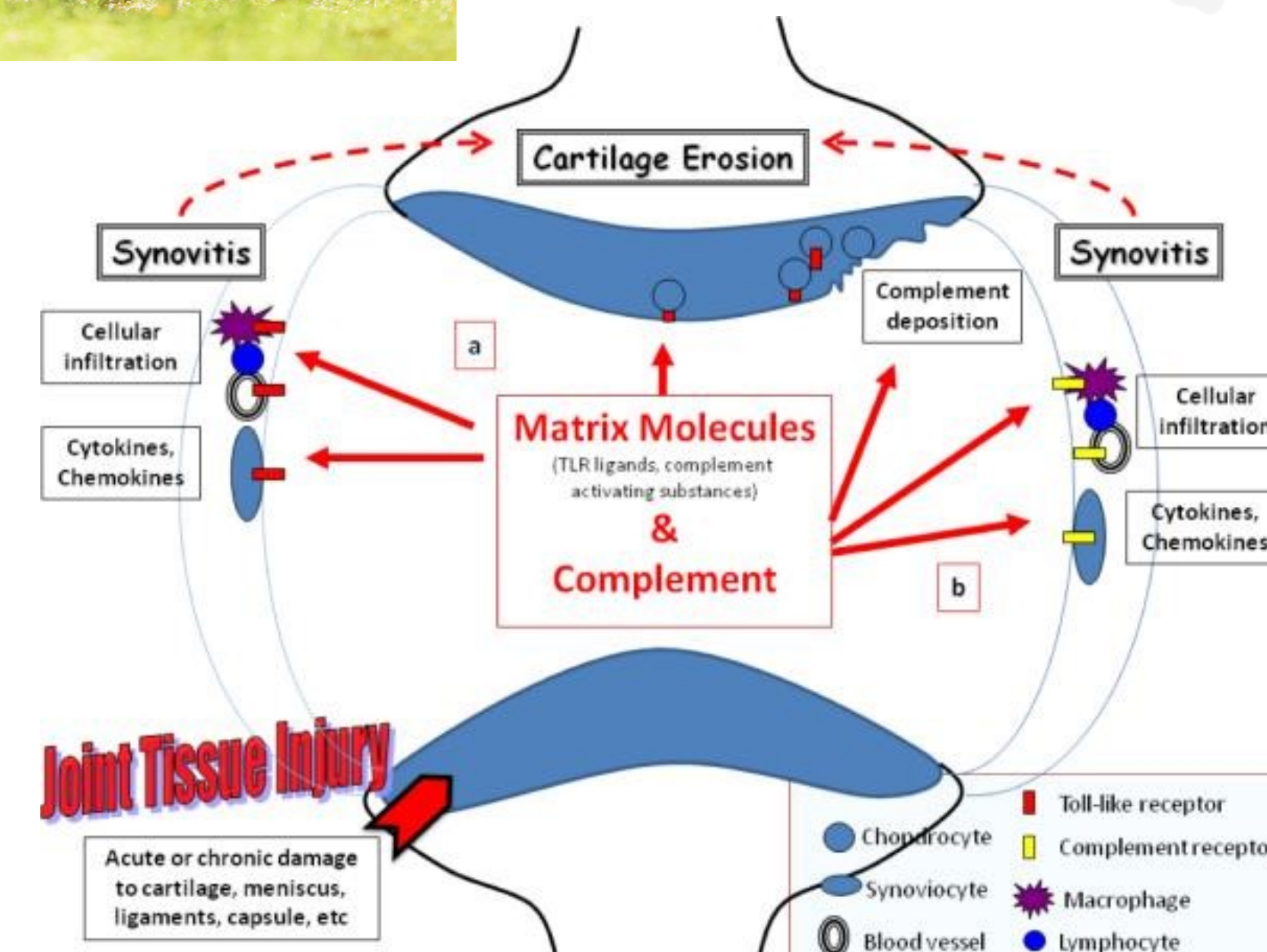


Elder pets are a growing share of the market

OA more common in dogs:

- overweight
- large breeds
- neutered

Osteoarthritis mechanisms



Osteoarthritis benefits from herbal medicine

4. Herbal medicine

Devil's claw, Boswellia serrata, Curcuma Longa and Ginkgo Biloba

Harpagophytum procumbens: inhibitory activity on the expression of COX-2 and mRNA specific for INOS gene

Boswellia serrata: inhibits the synthesis of leukotrienes, decreases IL1 and TNF-alpha

Curcuma longa: decreases IL1 and TNF-alpha, increases IL 10 Increases type II collagen syntesys

...Can we improve our pets health by selectively strenghtening their immune system with botanicals?

Yes!



CONTACTS



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EPO's extracts: how to claim the high-quality ingredients

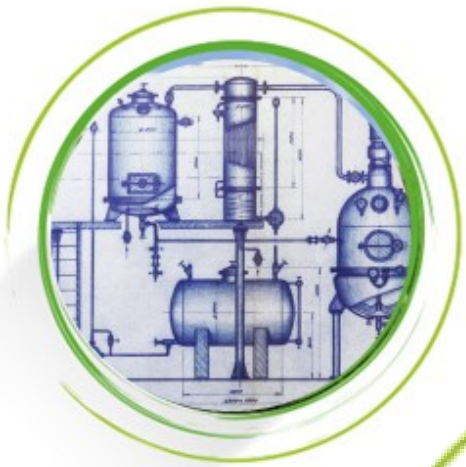
Violetta Insolia

Product and Marketing Specialist

EPO Srl



EPO srl



Established in Milan,

EPO Srl is a family company,

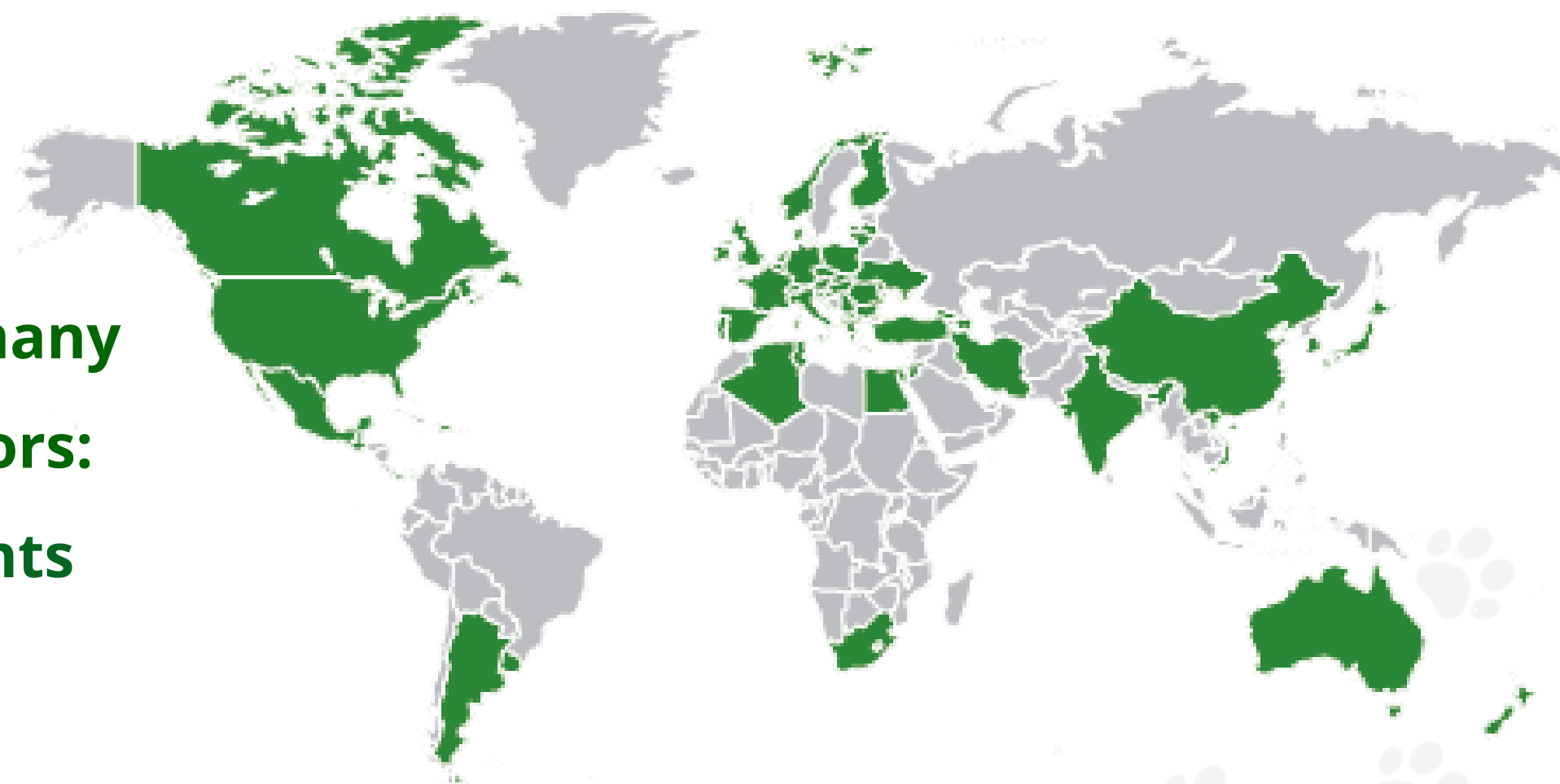
specialized in the production of high quality botanical extracts

since 1933



We export extracts in many Countries for different sectors:

- Food and food supplements
- Feed
- Cosmetics



The global pet food market is expected to grow from \$72.07 billion in 2020 to \$75.29 billion in 2021

- North America held the largest share of the market studied and accounted for around 37.6% of the overall market
- Asia-Pacific was the fastest-growing region for general pet food
- Middle East and Africa were the fastest-growing region for complementary pet food (supplements)



Source : Mordor Intelligence



During the start of the pandemic, **panic** was noticed by consumers **buying of dietary supplements and other pet food products**

CONSIDERATIONS ON COVID-19 IMPACT

On one hand, COVID-19 exerted a **negative impact on the supply chains**. Owing to the restrictions in the movement of raw materials, the pet food industry suffered initially in terms of supply and cash flow.

On the other hand, there was a steady growth on pet food segment in many parts of the world as **people adopted more pets** with the growing desire for companionship during the lockdown.

There was a consistent shift towards the **e-commerce platforms**: the players of this sector are making significant investments in increasing the brand value enhancement since there is an increase in consumer awareness about premium products

Over the long term, the **premiumization** and **humanization** trends are expected to remain the key drivers for the market growth during the forecast period (2021-2026). Due to the rising pet humanization trend worldwide, there is a growing interest of pet owners over their **pet health and nutrition**, which in turn is expected to boost the sales of organic, premium, and custom-made products over the study period.



Pet Dietary Supplements Market

will accelerate at a CAGR (Compound Annual Growth Rate) of over 5%
through 2020-2024



The Pet Dietary Supplements Market is projected to register a CAGR of 5.4% during the forecast period (2021-2026).

Humanization

Pet owners look like their animals



Animals look like their owners





A sort of 'extended family'

The shift from pet ownership to pet parenting

Over one-third of the households in the developed countries own a pet.

As pets have increasingly become viewed as family members, pet owners are willing to **increase their annual spending** on pet dietary supplements. This consumer trend toward pet surrogation coupled with rising health issues in pets is anticipated to create ample space for pet dietary supplements over the forecast period (2021-2026).





What is considered PREMIUM?

The shift from pet ownership to pet parenting

The market is driven by heavy influences from human nutrition, driving research toward **better** and **safer** food for pets with **high nutritional** and **dietary benefits**. Additionally, **locally-sourced** products and **ethically-sourced** products are propelling the market

All natural  – feed that contains minimally processed and no artificial ingredients

Organic products  – feed that grown without the use of pesticides, synthetic fertilizers or GMOs

Holistic approach  – feed that provides optimal nutrition and a meal that supports the overall well-being

Sustainability  – from economic, environmental and social point of view



EPO srl

THREE MAIN REASONS TO CHOOSE EPO EXTRACTS

QUALITY

- manufacturing process entirely made in Italy,
- full traceability
- validated analytical methods

SAFETY

- botanical species certified by DNA barcoding analysis,
- compliance with EU legislation on Food and Food Supplements

EFFICACY

- extracts with long traditional use,
- accurate quantification and standardization of bioactive compounds
- pre-clinical studies

ISO 9001:2015



CERTIFIED QUALITY
MANAGEMENT SYSTEM

ISO 9001:2015
certification

Intertek

GMP and FDA
21CFR111-117
for dietary supplements



DNA certified
extracts



GMP compliance
for a customized product



Kosher
certification



Organic
certification

- We follow a strict **HACCP protocol** with the identification of the CCP;
- We comply with the **EU Reg. 183/2005**;
- The extracts are carefully tested, from actives **standardization** to searching chemical and microbiological **contaminants**.
- We have a wide range of products: dry, soft, fluid, glycolic extracts and tinctures

THE DNA CERTIFIED EXTRACTS



At **EPO** the botanical identification of the raw materials is supported by the cutting-edge technique of DNA barcoding; the routinely use of it allowed **EPO** to be the first in Europe to launch a line of DNA certified extracts. **EPO** allows to use the "DNA certified extracts" logo on the packaging of customer's finished product. The procedure is simple and fast! Visit www.eposrl.com to download the list of DNA certified extracts and to learn more about it.

Catalogue preview

High-quality ingredients

EPO Srl offers a wide range of plant extracts as ingredients to produce complete and complementary feed.

The EPO extracts are classifiable as:

- **Feed additives**, according to EC Regulation n. 1831/2003 (annex I and II) and subsequent updates, belonging to 'sensory additives' category with the only flavouring property (cat. 2b).
- **Feed materials** according to EC Regulation n. 1017/2017, 767/2009 and subsequent updates.



Warning - The information found in this catalogue refers to overall current knowledge and Regulations concerning plant extracts together with their applications in feed industry. Feed additives and materials included here comply with EC Reg. 1831/2003, 1017/2017, 767/2009 and subsequent updates; however, EPO Srl declines any responsibility on the incorrect end-use of the extracts outside aforementioned Regulations' framework and in case of improper use in species of animals not permitted by the Regulations. The information reported above, do not waive end user's obligations to identify and control the product in relation to intended use. EPO Srl assumes no liability for damages of any nature resulting from incorrect use of products and for their commercialization in extra-European markets where the regulatory classification may be different. It is always advisable to consult with a veterinarian, the only qualified healthcare provider, who can make a diagnosis, prescribe a therapy, and suggest a correct feed formulation.



FEED ADDITIVES
(EC REG. 1831/2003)

Botanical name Common name	Botanical family Part of plant	Code	Type of extract	DNA 100% EPO	All species	Only for cat and dogs
<i>Arctium lappa</i> L. BURDOCK	Compositae (Asteraceae) Root	V3104702.RA	Dry extract ≥ 2.0 Inulin	 		
		V0104720.A	Fluid extract	 		
<i>Boswellia serrata</i> Roob. ex. Colebr. BOSWELLIA	Burseraceae Gum resin	V3536765A.1	Dry extract 65% boswellic acid			
<i>Citrus paradisi</i> Macfad. GRAPEFRUIT	Rutaceae Seed	V3125910.A	Dry extract (GSE) ≥ 10.0 Bioflavonoids			
		V3125950.A	Dry extract (GSE) ≥ 50.0 Bioflavonoids			
<i>Curcuma longa</i> L. TURMERIC	Zingiberaceae Rhizome	V3012100.A	Dry extract DER 4/1	 		
<i>Cynara scolymus</i> L. ARTICHOKe	Compositae (Asteraceae) Leaf	V3107602.A	Dry extract ≥ 2.5 Chlorogenic acid	 		
		V0207620.A	Fluid extract	 		



The case history of EkinACT®



EkinACT is a dry extract of *Echinacea purpurea* (L.) Moench standardized to contain 4% phenolic acids.



QUALITY

Made in Italy and full traceability from the field to the final extract

Official analytical method (EP and USP)



SAFETY

Botanical species certified by DNA barcoding analysis

Compliance with EU legislation on Food and Food Supplements



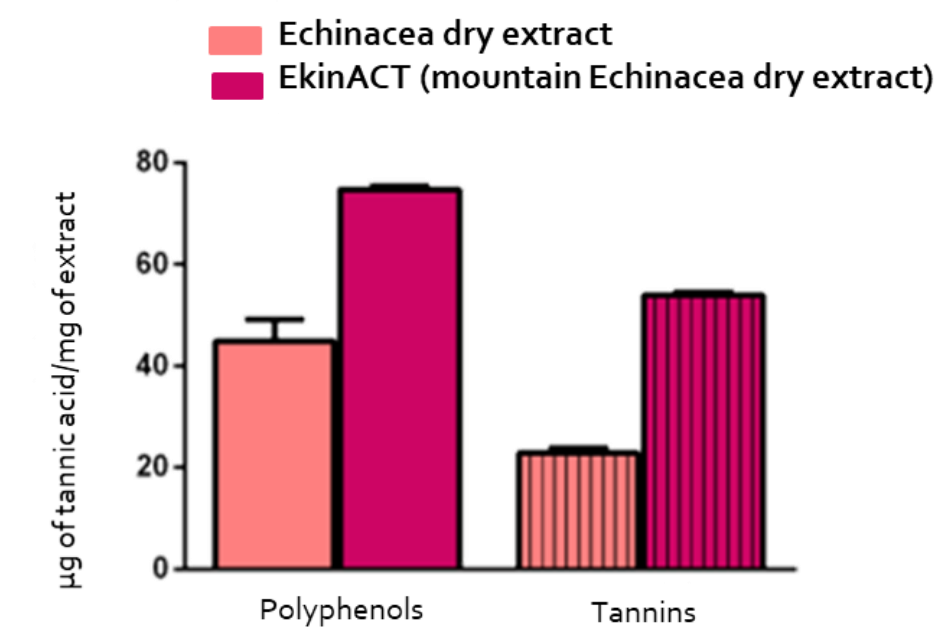
EFFICACY

Rich metabolic profile in accordance with the accepted traditional use

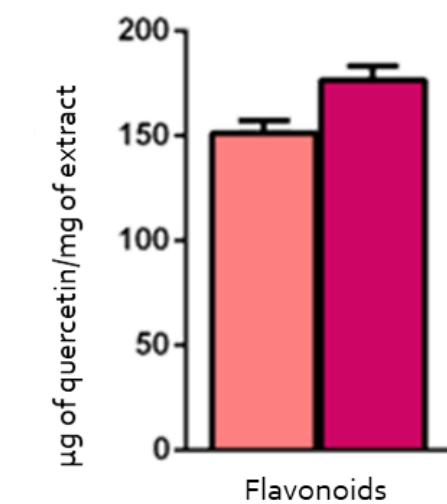
in vitro studies



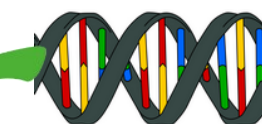
A



B



Echinacea



AATGCCGTATCGATTGCCCCAGTCAGGATCGATGCAT



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Thank you



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